Utah Department of Health

TB Control Program Manual

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Contents

Mission Statement

The mission of the TB Control/Refugee Health Program is to prevent, control and eliminate tuberculosis in Utah, by fostering community health partnerships with those who serve high risk and refugee populations through culturally appropriate health screening, education and referral.

We will accomplish our mission through: policy development, expert consultation, technical assistance, education, and surveillance.

These activities ultimately protect and promote public health in Utah.

INTRODUCTION

In partnership with the local health departments (LHDs) and health care providers, the Utah Department of Health, Bureau of Communicable Disease Control, TB Control/ Refugee Health Program is responsible for implementation of the Utah Administrative Code Communicable Disease Rule (R388-804), which outlines a multidisciplinary approach to communicable and infectious disease control. It emphasizes reporting, surveillance, isolation, treatment, and epidemiological investigation. This manual describes policies, protocols, and recommendations for the State of Utah. The protocols cover common as well as complex clinical issues that arise in the control of tuberculosis (TB). These protocols are based on recommendations of the Centers for Disease Control and Prevention (CDC), the American Thoracic Society (ATS), the Infectious Disease Society of America (IDSA), and the opinions of local and national experts in TB diagnosis, treatment, and control.

Although an attempt has been made to design a comprehensive manual, protocols cannot and should not substitute for clinical judgment. For most clients however, strict adherence to clinical protocols will result in improved care and the control of TB. Clinicians are strongly encouraged to seek consultation for issues related to individual cases that may not be fully discussed here.

TB Special measures for the Control of Tuberculosis

Purpose

The Statute gives the TB Control Program the authority to write rules to control tuberculosis. The purpose of this rule is to focus the efforts of tuberculosis control on disease elimination. The standards outlined in this rule constitute the minimum expectations in the care and treatment of individuals diagnosed with, suspected to have, or exposed to tuberculosis.

Policy and Procedure

This rule establishes standards for the control and prevention of tuberculosis as required by section 26-6-4, Section 26-6-6, Section 26-6-7, Section 26-6-8, and Section 26-6-9 of the Utah Communicable Disease Control Act and Title 26, Chapter 6b, Communicable Diseases - Treatment, Isolation, and Quarantine Procedures.

References

State of Utah, Department of Health Communicable Disease Rule, Special Measures for the Control of Tuberculosis.

Quarantine Manual

Follow-up Responsibility

TB Controller
TB Control Program Manager

Program Goals and Objectives

Program Objectives:

Objective 1.1: Ensure that at least 90% of individuals with a high likelihood of having TB receive a medical evaluation within 14 days for active TB disease.

Objective 1.2: Ensure that 90% of clients with active TB disease are placed on appropriate therapy following CDC/ATS guidelines.

Objective 1.3: Continue aggressive assessment of the need and use of incentives and enablers for 100% of newly diagnosed TB cases and high-risk contacts of cases.

Objective 1.4:. Ensure that at least 90% of clients with active TB disease are provided directly observed therapy. Ensure that at least 75% of contacts to sputum AFB-smear positive cases who are children under the age of four receive directly observed preventive therapy.

Objective 1.5: Ensure that local health departments locate and evaluate at least 90% of refugees and immigrants classified as A, B1 or B2 within 45 days of notification for active TB disease or latent TB infection.

Objective 1.6: Collaborate with local health departments, the Utah Department of Health HIV/AIDS Surveillance Program, HIV Counseling and Testing Program, and HIV Treatment and Care Program to ensure that at least 75% of all newly diagnosed TB cases age 25 - 44 are offered counseling and testing for HIV and referred for treatment if found to be HIV positive.

Objective 1.7: Ensure that at least 90% of patients with newly diagnosed TB, for whom therapy for one year or less is indicated, will complete therapy within 12 months.

Objective 1.8: Continue to provide TB medications to 100% of contracted pharmacies throughout the state in collaboration with Utah's 12 local health districts and receive monthly inventory tracking of these medications from 90% of the contracted pharmacies with inventory.

Objective 1.9: Continue to provide an effective system of housing support for at least 90% of clients with active tuberculosis disease who are homeless or in a high-risk situation for non-completion of therapy.

Objective 1.10: Ensure facilities are available for clients requiring court-ordered treatment, isolation, and quarantine per Utah Health Code, Chapter 26-6-6b.

CONTACT INVESTIGATION

Program Objectives:

Objective 2.1: Ensure that contact identification is initiated 80% of the time within three working days of report to local health departments of sputum AFB-smear positive suspects with a high index of suspicion for TB or confirmed TB cases.

Objective 2.2: Contacts will be identified for at least 90% of newly reported sputum AFBsmear positive TB cases.

Objective 2.3: At least 85% of contacts of newly reported sputum AFBsmear positive TB cases will be evaluated for TB infection and disease.

Objective 2.4: At least 75% of infected contacts to sputum AFB-smear positive TB cases who are started on treatment for latent TB infection will complete therapy.

TB SURVEILLANCE/REPORTING

Program Objectives:

Objective 3.1: Increase by 10%, collaboration with local health departments, correctional facilities and substance abuse treatment programs to encourage active case finding, treatment and completion of therapy of active TB disease/latent TB infection in drug treatment centers, prisons and jails.

Objective 3.2: Increase by 10%, collaboration with local health departments and community based organizations serving high-risk populations to encourage active case finding, treatment and completion of therapy.

Objective 3.3: Maintain an active surveillance/case finding system. This system will facilitate reporting at least 90% of suspected and confirmed TB cases to the Utah Department of Health and/or local health departments within three days of the first occurrence of suspected/confirmed TB diagnosis, a positive AFB laboratory smear, positive Nucleic Acid Amplification test or positive *M. tuberculosis* culture.

Objective 3.4: Ensure that all verified cases of tuberculosis are reported with at least 95% of core data items being complete. Verified cases of tuberculosis will be reported to the CDC at least monthly.

Objective 3.5: Drug susceptibility results will be reported for at least 90% of all newly reported culture-positive tuberculosis cases.

Objective 3.6: HIV status will be reported for at least 75% of all newly reported TB cases age 25 - 44.

Objective 3.7: Ensure that 100% of TB surveillance data and HIV test results are kept confidential and all data files secure, conforming to the confidentiality requirements of the HIV/AIDS Surveillance Program.

Objective 3.8: Continue to provide funding to facilitate access to culturally and linguistically appropriate resources to the Salt Lake Valley, Weber/Morgan and Utah County Health Departments to care for TB suspects/cases, contacts and TB skin test converters in ethnically diverse populations.

Objective 3.9: Provide at least 15 hours of technical assistance to local health departments and community providers serving American Indians/Alaskan Natives living both on and off the designated reservations.

HUMAN RESOURCE DEVELOPMENT

Program Objectives:

Objective 4.1: Continue to hold Advisory Committee meetings biannually. Broaden the scope and complexity of issues dealt with during these meetings. Identify and invite participation of additional community stakeholders to the committee.

Objective 4.2: Discuss the strategic TB Control and Elimination Plan with the Advisory Committee. Reestablish priorities and objectives on a biannual basis.

Objective 4.3: Provide at least 975 hours of state-of-the-art education to health care providers and case managers practicing in TB.

References

Utah Department of Health, Tuberculosis Elimination Cooperative Agreement

Follow Up Responsibility

TB Control Program Manager

Tuberculin Skin Testing

Purpose

To establish a policy for administrating the tuberculin skin test (TST), also known as the Mantoux tuberculin skin test. TST screening should be focused on populations most at risk for infection, or if infected, at risk for disease. TST is not necessary for individuals with a documented previous positive TST result.

Policy

Targeted tuberculin skin testing for latent tuberculosis infections (LTBI) is a strategic component of tuberculosis (TB) control. It identifies persons at high risk for developing TB disease who would benefit from treatment, if detected. Persons with increased risk for developing TB disease include those recently infected with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB disease (ATBD). Infected persons who are at high risk for developing ATBD should be considered for treatment of LTBI regardless of age.

Targeted tuberculin skin testing programs should be conducted only among high-risk persons. Persons administering the TST should be properly trained in the administration and reading of the TST. **The decision to administer a tuberculin skin test (TST) should be a decision to assess the client and consider treatment of LTBI if the person has a positive TST result.** Screening persons at low risk for TB is discouraged because this test has poor predictive value in unselected (low risk) populations and diverts resources away from higher priority TB control activities such as the identification and treatment of active cases and contact investigation.

It is recommended that the TST be administered to the following groups:

- Close contacts of persons known or suspected to have TB
- Foreign-born persons, including children, who have recently arrived from areas that have a high incidence of TB
- Health care workers who serve high-risk clients
- Some medically under-served, low-income populations as defined locally
- Employees or residents of high risk congregate settings such as hospitals, correctional facilities, homeless shelters, nursing homes, or drug treatment centers
- High-risk populations, defined locally as having increased prevalence of TB. In Utah this would include Asians, Pacific Islanders, Hispanics, Native Americans, migrant farm workers, homeless persons and returned LDS missionaries

- Mycobacterial laboratory personnel
- Persons who inject illicit drugs or other high risk substance users
- Infants, children, and adolescents exposed to adults in high-risk categories

The following persons are at higher risk for TB disease once infected and testing should be considered if they have risk of exposure.

- Persons with HIV infection
- Persons who have medical conditions known to increase the risk for disease if infection occurs (diabetes, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, hematologic and reticuloendothelial diseases, end-stage renal disease, intestinal bypass or gastrectomy, chronic malabsorption syndromes, low body weight (10% or more below ideal)
- Rheumatoid arthritis clients taking infliximab (Remicade), etanercept (Enbrel), or adalimumab (Humira)

Procedure

a. The TST should be administered by the Mantoux technique as described in the CDC Core Curriculum, Fourth Edition, 2000. **Multiple puncture tests (e.g., the Tine Test) should not be used**. Purified protein derivative (PPD), the antigen used in the TST, should be stored between 2&8°C (35&46°F) and protected from light. Vials in use more than 30 days should be discarded due to possible oxidation and degradation, which may affect potency. Syringes should not be pre-filled and the use of safety syringes is recommended. Gloves are optional, consult the infection control requirements of your facility. The PPD vial is a one-way vial and care should be taken to avoid inserting air or solution back into the vial. An informed consent to administer the TST is recommended.

b. Reading of the TST should only be done by a trained health care worker; clients should **never** be allowed to read their own reaction. Measure only the hard, swollen area known as induration and record the size of the induration in millimeters, not as “positive” or “negative.” Results are read 48-72 hours after administering the test. If the client fails to return for the scheduled reading but returns up to a week after the test administration, examine the test site and measure any induration present. If there is no reaction or it is too small to be classified as positive, repeat the test.

c. Classifying the results should be done using: A Guide to the Classification of Mantoux Tuberculin Skin Test (TST) Results and the Management of TST-Positive and Other Clients. Utah Department of Health Tuberculosis Control/Refugee Health Program, September 2005.

d. Tuberculin skin testing is not contraindicated for persons who have been vaccinated with Bacillus Calmette-Guérin (BCG), and the skin test results of such persons are used to support or exclude the diagnosis of LTBI. The booster phenomenon may occur among persons who have had a prior BCG vaccination. A diagnosis of LTBI and the use of treatment for infection should be considered for any BCG-vaccinated person who has a TST reaction of ≥10mm of

induration, especially if any of the following circumstances are present:

- The vaccinated person is a contact of a person who has ATBD, particularly if the person is infectious and has transmitted *M. tuberculosis* to others
- The vaccinated person was born or has resided in a country in which the prevalence of TB is high
- The vaccinated person is exposed continually to populations in which the prevalence of TB is high (e.g., some health care workers, employees and volunteers at homeless shelters, and workers at drug-treatment centers)

e. The absence of a reaction to the tuberculin skin test does not rule out the diagnosis of TB disease or infection. In immunosuppressed persons, delayed-type hypersensitivity responses such as tuberculin reactions may decrease or disappear. This condition, known as anergy, may be caused by many factors, such as HIV infection, severe or febrile illness, measles or other viral infections, Hodgkin's disease, sarcoidosis, live-virus vaccination, or the administration of corticosteroids or immunosuppressive drugs. On average, 10% to 25% of clients with TB disease have negative reactions when tested with a tuberculin skin test. **Do not rule out diagnosis based on a negative skin test result. Consider anergy in persons with no reaction if:**

- HIV infected
- Overwhelming TB disease
- Severe or febrile illness
- Viral infections
- Live-virus vaccinations
- Immunosuppressive therapy/disease

Anergy skin testing is no longer routinely recommended

f. In some people who are infected with *M. tuberculosis*, delayed-type hypersensitivity to tuberculin may wane over the years. When these people are tuberculin skin tested many years after infection, they may have a negative reaction. However, this skin test may stimulate (boost) their ability to react to tuberculin, causing a positive reaction to subsequent tests. This booster reaction may be misinterpreted as a new infection. The booster phenomenon may occur at any age: its frequency increases with age and is highest among older persons. Boosted reactions may occur in persons infected with nontuberculous mycobacteria or in persons who have had a prior BCG vaccination.

Two-step testing is used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection. If the reaction to the first test is classified as negative, a second test should be done 1-3 weeks later. A positive reaction to the second test probably represents a boosted reaction (past infection or prior BCG vaccination). On the basis of this second test result, the person should be classified as previously infected and cared for accordingly. This would not be considered a skin

test conversion. If the second test result is also negative, the person should be classified as uninfected. In these persons, a positive reaction to any subsequent test is likely to represent new infection with *M. tuberculosis* (skin test conversion). Two-step testing should be used for the **initial** skin testing of adults who will be retested periodically, such as health care workers and correctional staff.

g. False negative TST reactions may be due to:

- Anergy
- Recent TB infection
- Very young age (< 6 months age)
- Live virus vaccinations (see below)
- Some viral infections (measles, mumps, chickenpox, and HIV)
- Corticosteroids and other immunosuppressive agents at doses of 2mg/kg/day or greater for 2 or more weeks.

Vaccination with live viruses (e.g. Measles, Mumps, Rubella, Varicella, Typhoid oral, and Yellow Fever) may also interfere with TST reactivity and cause false negative reactions. TST should be done on either the same day as vaccination with live virus or 4-6 weeks after vaccination.

h. False positive TST reaction may be due to:

- Nontuberculous mycobacteria
- BCG vaccination

i. Tuberculin skin testing in pregnant women is safe and reliable. Routine TST screening among pregnant women is not indicated because pregnancy itself does not increase the risk for TB infection. However, pregnant women at high risk for TB infection or disease should be tested.

j. Adverse reations to a TST (e.g. blistering, ulcerations, necrosis) should be reported to the Food and Drug Administration's Med Watch Program at 1-800-FDA-1088 or via the internet at www.fda.gov/medwatch .

References

CDC Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition, 2000. (Page 25-33)

Utah Department of Health Tuberculosis Control/Refugee Health, A Guide to the Classification of Mantoux Tuberculin Skin Test (TST) Results and the Management of TST-Positive and Other Clients., March 2005

Tuberculosis Associated with Blocking Agents Against Tumor Necrosis Factor - Alpha - California, 2002 - 2003 - MMWR 2004; 53 (No.30).

Treatment of latent Tuberculosis Infection in Children and Adolescents; Pediatrics 2004; 114;1175-1201.

American Thoracic Society Diagnostic Standards and Classification of Tuberculosis in Adults and Children 1999. (Page 1387-1391)

Follow-up Responsibility

TB Nurse Consultant

Treatment of Latent Tuberculosis Infection (LTBI)

Purpose

To establish a policy for evaluation and treatment of individuals found to have a positive tuberculin skin test (TST).

Policy

Individuals found to have a positive tuberculin skin test should be carefully evaluated to rule out active TB disease (ATBD). If no evidence of ATBD is found then evaluate for treatment of latent TB infection (LTBI). Targeted testing programs should be designed to identify persons who are at higher risk for TB and who would benefit from treatment of LTBI. The decision to test is a decision to evaluate for treatment!

Procedure

a. Medical evaluation should include a history of

- Symptoms of disease
- History of TB exposure, infection, or disease
- Past TB treatment
- Demographic risk factors for TB
- Medical conditions that increase risk for TB disease
- Bacteriologic or histologic exam
- Medical contraindications for treatment of LTBI
- Current medications that may be affected by use of INH or Rifampin

b. The Mantoux Tuberculin Skin Test (TST) is the preferred method of testing for TB Infection in adults and children. Classification of a positive test is found in A Guide to the Classification of Mantoux Tuberculin Skin Test Results and the Management of TST-positive and Other Clients. March 2005

c. All individuals being considered for treatment should undergo a chest x-ray to rule out active pulmonary TB disease. Children younger than 5 years old (i.e., up to the day of the fifth birthday) should undergo both a posterior-anterior and a lateral chest x-ray. All other individuals should receive a posterior-anterior chest x-ray only; additional x-rays should be done at the physician's discretion. Consultation with the Utah State Pulmonologist and/or Pediatric Consultant is available. A chest x-ray should be given **even during the first trimester**, to pregnant women who:

- Have symptoms that are highly suggestive of TB disease (cough, fever, night sweats, chest pain etc.), **or**
- Are HIV seropositive and (1) TST positive or (2) TST negative but have been in close contact with a person who has pulmonary or laryngeal TB disease, **or**
- Are TST positive and have been in close contact with a person who has pulmonary or laryngeal TB disease.

Other pregnant women who have a positive TST reaction should be advised to obtain a chest x-ray after the end of the first trimester. An appropriate lead shield should be used for chest x-rays in pregnant women.

d. Persons in the following high-risk groups should be given the highest priority for treatment of LTBI if they have positive skin test results ≥5mm of induration:

- HIV-positive persons
- Recent contacts of a TB case
- Persons with fibrotic changes on chest radiograph consistent with old TB
- Clients with organ transplants
- Other immunosuppressed clients

In addition, persons in the following high-risk groups should be considered for treatment of LTBI if their reaction to the TST is ≥10mm of induration:

- Recent arrivals from high-prevalence countries
- Intervenous drug users
- Residents and employees of high-risk congregate settings
- Mycobacteriology laboratory personnel
- Persons with clinical conditions that make them high-risk
- Children <4 years of age, or children and adolescents exposed to adults in high-risk categories
- Returned LDS missionaries

Persons with no known risk factors for TB may be considered for treatment of LTBI if their reaction to the tuberculin test is ≥15 mm of induration. This group should be given the lowest priority for treatment efforts.

Some contacts that have a negative tuberculin skin test reaction (<5mm of induration) should be evaluated for treatment of LTBI, after TB disease has been ruled out. These contacts include children less than 4 years of age, immunosuppressed persons, and others who may develop TB disease quickly after infection. Close contacts that have a negative reaction to an initial TST should be retested 8 weeks after they were last exposed to TB. Treatment for latent infection may be discontinued if the skin test result is again negative **and** if the person is no longer exposed to TB. However, persons known to have or suspected of having HIV infection and other immunocompromised persons should be given treatment for LTBI regardless of their skin test reaction.

Because of their age, infants and young children with LTBI are known to have been infected recently, and thus are at a high risk of their infection progressing to disease. Infants and young children are also more likely than older children and adults to develop life-threatening forms of TB. Children less than 4 years of age who are close contacts of person with ATBD should receive treatment for LTBI even if the TST and x-ray do not suggest infection. A second TST should be placed 8 weeks after the last exposure to infectious TB. Treatment for LTBI can be discontinued if the second test placed at least 8 weeks after exposure was also negative and the infant is at least 6 months of age.

e. Before treatment for LTBI is initiated and after ATBD ruled out, the clinician should discuss the risk and benefits of treatment with the client, determine contraindications to treatment and check for adverse reactions to current drugs which have known interactions with drugs used for LTBI. Discuss adherence issues with the client. Written consent to begin therapy must be obtained and maintained in the client record. Commitment to complete the 6 to 9 month course of treatment should be obtained.

f. Medication used for the treatment of LTBI in adults is described in detail in the Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000, and ATS/CDC/IDSA Treatment of Tuberculosis **Since the publication of the Core Curriculum and General Guidelines on the Management of Tuberculosis Infection and Disease, changes have been made for the use of rifampin and pyrazinamide and are included in the MMWR referenced at the end of this chapter. This regimen is no longer recommended.**

Drugs	Duration	Interval	HIV-	HIV+
Isoniazid (INH)	9	Daily	A (II)	A (II)
		Twice Weekly	B (II)	B (II)
Isoniazid (INH)	6	Daily	B (I)	B (I)
		Twice Weekly	B (II)	B (II)
Rifampin (RIF)	4	Daily	B (II)	B (II)

* **A**- Prefered: **B**- acceptable alternative; **C**- offer when A and B cannot be given
* **I**- Randomized clinical trial data; **II**- Data from clinical trials that are not randomized or were conducted in other populations; **III**- expert opinion

g. The recommended regimen for treatment of LTBI in children is INH for 9 months. If INH cannot be tolerated Rifampin can be used for 4 months.

h. Completion of therapy should be based on the total number of doses administered, not duration of therapy. If treatment is interrupted the recommended number of doses of the regimen should be provided within a certain time frame.

- A 6-month regimen consisting of 180 doses of INH can be given over a 9-month period of time.
- A 9-month regimen consisting of 270 doses of INH can be given over a 12-month period of time.

The entire regimen should be restarted if interruptions were frequent or prolonged enough to preclude completion of doses in the time frames specified. When therapy is restarted after an interruption of more than 2 months, a medical examination to exclude active disease is indicated.

i. Clients who are at high risk of developing active TB disease who are prescribed treatment for LTBI but have interruptions in treatment should be encouraged to complete the regimen. However, if the client has failed three attempts to complete treatment, no further efforts should be made. Incentives and enablers may be used to encourage completion in high risk clients such as contacts, young children and HIV infected individuals.

j. Monitoring for side effects may include baseline laboratory testing for clients whose initial evaluation suggest a liver disorder, who use alcohol regularly and others who are at risk of chronic liver disease. Baseline testing is also indicated for clients with HIV infection, women who are pregnant or immediately post partum. Testing should be considered on an individual basis, particularly for clients who are taking other medications for chronic medical conditions. See Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000 for more details.

Monthly monitoring is required for adherence to prescribed regimen, signs and symptoms of active TB disease, and signs and symptoms of hepatitis. Face-to-face visits and assessments are required. Consultation with the client's primary care physician and/or the Utah State Pulmonologist is recommended when adverse reactions occur.

Peripheral neuropathy is associated with the use of isoniazid (INH) but is uncommon at doses of 5mg/kg. Persons with conditions in which neuropathy is common, e.g., diabetes, uremia, alcoholism, malnutrition, HIV-infection, pregnant women and persons with a seizure disorder, may be given pyridoxine (vitamin B6) 10-50mg/day with INH.

k. Health care providers often do not realize that their clients are not following recommendations. It is very important to determine that clients are taking medications as prescribed and to have a high index of suspicion of non-adherence. There are several methods for assessing adherence:

   - Ask the client
   - Communicate effectively
   - Help the client to remember
   - Listen carefully and ask the client to report any problem with taking the medications
   - Monitor appointment keeping, medication refill, and pick-up
   - Monitor pills (perform pill counts)
   - Directly observe the clients swallowing each dose of medication.
   - Directly observed therapy (DOT) is recommended for clients who are at high risk for progression to disease and whose adherence is questionable (e.g. IV drug users, homeless persons, children, contacts to drug resistant TB and persons with a history of non-adherence with any medical treatment regimen. DOT is required for all intermittent regimens.

l. A physician or primary care provider must decide the appropriate duration of treatment for LTBI. Both the 6 month and 9 month regimen of INH are acceptable. The client should be advised to return to the clinic or report to the public health nurse any time he/she develops symptoms suggestive of ATBD.

m. Upon completion of therapy, the client should be informed that repeat chest x-rays are not necessary and **repeat TSTs are not advised**. The client should be given completion of LTBI documentation. Selected high-risk individuals such as HIV infected persons who cannot or will not take preventive therapy may have periodic chest x-rays at the discretion of the primary care provider.

n. The TB Control Program provides medication for LTBI at no cost to those clients without health insurance that would cover the cost of the medication. See section on **Ordering Drugs** for more detailed information.

o. Notify the TB Control Program for adverse reactions to medications taken for LTBI at 1-801-538-6096.

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000. (Page 53-60)

MMWR Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection, August, 2003

Utah Department of Health Tuberculosis Control/Refugee Health, A Guide to the Classification of Mantoux Tuberculin Skin Test Results and the Management of TST-Positive and Other Clients.

ATS/CDC/IDSA Treatment of Tuberculosis, June 2003

Follow-up Responsibility

TB Nurse Consultant

Active Tuberculosis Disease Initial Evaluation (ATBD)

Purpose

To establish a policy for the initial evaluation of active TB disease (ATBD).

Policy

A diagnosis of tuberculosis (TB) may be considered for any client who has an abnormal chest x-ray consistent with TB or for any client who has a persistent cough lasting 3 weeks or more or other signs or symptoms compatible with TB including bloody sputum, chest pain, night sweats, fatigue, weight loss, loss of appetite or persistent fever. A qualified medical provider should make the diagnosis. The index of suspicion for TB should be very high in areas of high prevalence or among groups with a high prevalence of TB.

In Utah during 2005, 20% of TB cases were exclusively extrapulmonary with an additional 10% with pulmonary and extrapulmonary TB. The symptoms of TB depend on the site affected. TB of the spine may cause pain in the back; TB of the kidney may cause blood in the urine. Extrapulmonary TB should be considered in the differential diagnosis of ill persons who have systemic symptoms and who are at high risk for TB. Pulmonary TB should always be evaluated when extrapulmonary TB is diagnosed.

Procedure

a. Persons for whom a diagnosis of TB is being considered should receive a complete medical history which should include questions pertaining to risk factors for TB exposure, infection or disease, symptoms of TB, underlying health conditions, risk factors for human immunodeficiency virus (HIV) infection or HIV antibody status, and information about contacts (especially high risk contacts, where immediate action may be necessary). If the client received prior treatment for TB and the drug regimen was inadequate or if the client did not adhere to therapy, TB may recur and may be drug resistant. Clients with an unknown or negative HIV status should be referred for HIV counseling and testing.

b. A physical examination is an essential part of the evaluation of any client. It cannot be used to confirm or rule out TB, but it can provide valuable information about the client's overall health and other factors that may affect how TB is treated.

c. If there is no documentation that a tuberculin skin test (TST) has been performed, it should be done, unless cultures for *M. tuberculosis* are positive.

d. Clients who have a positive TST result or symptoms suggestive of TB (regardless of TST results) should be evaluated with a chest x-ray. Radiographic abnormalities that strongly suggest ATBD include upper-lobe infiltration, particularly if cavitation is seen, and patchy or nodular infiltrates in the apical or subapical posterior upper lobes or the superior segment of the lower lobe. If abnormalities are noted, or the client has symptoms suggestive of extrapulmonary TB, additional diagnostic tests should be conducted.

   Abnormalities on chest x-ray may be suggestive of, but are never diagnostic of TB. Chest x-rays may be used, however, to rule out the possibility of TB in a person who has a positive reaction to the TST and no symptoms of disease.

   The radiographic presentation of pulmonary TB in HIV infected clients may be unusual. Typical apical cavitary disease is less common among such clients. They may have infiltrates in any lung zone, a finding that is often associated with mediastinal and/or hilar adenopathy, pleural effusion or they may have a normal chest radiograph, although this latter finding rarely occurs.

   Old, healed TB can produce various radiographic findings such as pulmonary nodules, with or without fibrotic scars or visible calcifications. Nodules and fibrotic scars may contain slowly, multiplying tubercle bacilli with the potential for future progression to active TB.

   Pregnant women who are strongly suspicious of having ATBD should undergo a chest x-ray without delay, even during the first trimester. **A lead shield should be used for all chest x-rays in pregnant women.**

   Clients suspected of having extrapulmonary TB disease **should** undergo a chest x-ray to rule out pulmonary TB disease.

   The TB Control Program consults with expert pulmonologists to provide interpretations for suspected/known TB cases in both adults and children. Consult with the TB Control Program for information.

e. Bacteriologic tests are performed on specimens for TB diagnostic purposes:

- Smear examination - the specimen is concentrated, placed on a slide, and stained with a solution that detects acid-fast bacilli (AFB). Many TB clients have negative AFB smears.
- Culture of the specimen for AFB - the specimen is placed in a special media that allows mycobacterial growth. Further biochemical, and DNA tests are used to identify the type of AFB if growth occurs. Positive cultures for *Mycobacterium tuberculosis* complex (MTB) confirm the diagnosis of TB: however TB may also be diagnosed on the basis of signs and symptoms in the absence of a positive culture.
- Direct tests for Mycobacterium tuberculosis complex (MTBC): Respiratory specimens may be tested directly for the presence of MTBC by the detection of genetic material in the sample. Contact the TB Control Program for availability and instructions.
- Susceptibility testing from cultures positive for MTB complex - the organism is tested for resistance to drugs commonly used to treat TB. Isoniazid, rifampin, ethambutol, streptomycin and pyrazinamide are routinely tested.
- DNA fingerprinting is used to identify specific strains of TB and is a tool to track TB transmission. Related isolates show the same pattern. It can also be used to identify lab contamination.

Sputum samples should be obtained for smear and culture examination when pulmonary or laryngeal TB is suspected. Three early morning samples collected on 3 consecutive, separate days should be collected **preferably before drugs are started** (see section on collection of specimens in section two for more details). Because TB can also occur in almost any anatomical site, a variety of other clinical specimens (e.g. urine, cerebrospinal fluid, pleural fluid, pus, or biopsy specimens) should be submitted for examination when extrapulmonary TB disease is suspected. If a diagnosis of pulmonary TB disease cannot be established from sputum, other procedures may be necessary, including bronchoscopy and gastric aspiration.

The following is a guide to specimen smear and culture results:

If AFB Smear is:	and, If Culture is:	Interpretation and Actions
Positive	Positive for (AFB)	Assume MTB until proven otherwise; may be later identified as Non-tuberculosis mycobacteria (NTM).
Positive	Positive for (MTB)	Diagnosis of active TB disease. Reportable within 24 hours.
Negative	Positive for MTB	Same interpretation and actions as above.
Positive	Positive for non-tuberculosis mycobacteria (NTM)	Not infected with MTB, not considered contagious. Refer to primary care provider for treatment.
Negative	Positive for NTM	No bacteriological evidence for MTB;not considered contagious. In many such cases the NTM is a contaminant or colonizer
Negative	Negative for MTB and NTM	No bacteriologic evidence for MTB. If client has clinical symptoms not explained by another diagnosis and the suspicion for MTB is high, may still have active infection with MTB. Consult with TB Control Program.
Positive or Negative	Mycobacterium still present	Once identified as MTB do not probe each specimen. If still present after 2 months re-probe and then every month after.

f. A culture result of MTB or *M. Tuberculosis* complex provides a diagnosis of TB. However, a false-positive culture should be considered when the results do not fit the client's clinical status. Clients having only one positive culture should be re-evaluated for the possibility that the culture may be a false positive.

Other mycobacteria (*M. Avium* complex (MAC), *M. kansaii*, *M. chelonae*) may cause pulmonary disease but are not contagious. These organisms will be identified on final culture. Additionally, this organism may also be present intermittently in small numbers and may not be pathogenic. Although uncommon, a person may be infected with more

than one type of mycobacteria at any given time. See section on Collection of Samples for Testing for Tuberculosis in this manual for more details.

g. Clients who are suspected or diagnosed with ATBD must be reported to the TB Control Program within 24 hours.

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000. (Page 39-46)

American Thoracic Society Diagnostic Standards and Classification of Tuberculosis in Adults and Children September 1999. (Page 1377-2000)

ATS/CDC/IDSA Treatment for Tuberculosis, June 2003

NTCA/CDC A Guide to the Application of Genotyping to Tuberculosis Prevention and Control ,June 2004

Basic Guidelines for Treating Active Tuberculosis Disease

Purpose

To establish a policy for treatment of clients who have confirmed active TB disease (ATBD) (e.g. clients with positive cultures for *Mycobacterium tuberculosis* complex (MTB) or a clinical diagnosis by a qualified health care provider) or clients who are considered highly likely to have ATBD.

Policy

Clients who have confirmed ATBD (e.g. clients with positive cultures for MTB or a clinical diagnosis by a qualified health care provider) or clients who are considered highly likely to have ATBD should be started on appropriate treatment. It is not necessary to wait for laboratory confirmation of *Mycobacterium tuberculosis* complex (MTB) before starting treatment.

Procedure:

a. **The responsibility for successful treatment is clearly assigned to the public health provider or private provider and not to the patient. The private physician is carrying out a public health function with responsibility not only for prescribing an appropriate regimen but for successful completion of therapy.**

b. Treatment regimens must contain multiple drugs to which the organism is susceptible. The administration of a single drug or the addition of a single drug to a failing regimen can lead to the development of a strain of TB resistant to that drug. The preferred regimen for treating ATBD consists of an initial 2-month phase of four drugs: isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB) followed by a 4 to 7 month continuation phase of isoniazid and rifampin. Ethambutol can be discontinued when drug susceptibility results show the infecting organism to be fully drug-susceptible. See ATS/CDC/IDSA Treatment of Tuberculosis, 2003 for more details on medications.

c. Extended treatment is recommended for patients with drug-susceptible pulmonary tuberculosis who have cavitation noted on the initial chest film and who have positive sputum cultures at the time 2 months of treatment is completed. Treatment may also be extended with only one of the above risk factors: extensive radiographic disease, HIV infection, or other forms of immunosuppression.

d. Pyridoxine (Vitamin B-6) is recommended for some individuals receiving INH as part of their treatment regimen to prevent peripheral neuropathy. It should be used in persons

at risk for neuropathy (nutritional deficiency, HIV infection, renal failure diabetes and alcoholism), as well as pregnant women and breast feeding women.

e. Research has shown that non-compliance with self-administered treatment for ATBD leads to high failure rates and development of drug resistance. Therefore it is **required** that **all clients** be on **directly observed therapy (DOT).** This includes both pulmonary and extrapulmonary TB.

f. Clinical experience suggests that clients being managed by DOT administered 5 days a week have a rate of successful therapy equivalent to those being treated 7 days a week. Thus, a daily DOT schedule may be given on a 5 day a week or 7 day a week schedule.

g. TB medications should be administrated together as a single dose leading to higher and potentially more effective serum concentrations.

h. TB transmission prevention precautions **must** be followed for clients who are known or suspected of having ATBD who are sputum smear positive for acid fast bacilli. Clients with negative sputum smears for acid fast bacilli with positive cultures for *Mycobacterium tuberculosis* complex may still transmit TB especially if coughing.

i. Patients are not considered infectious if they meet **all** the following criteria:

- They are on adequate therapy for 2-3 weeks
- They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
- They have **three** negative AFB sputum smear results collected 8-24 hurs apart, with at least one being an early morning specimin.

j. Clients should be monitored bacteriologically at least every 2-4 weeks until cultures convert to negative, if any new symptoms develop, or if client is not improving. Cultures reported as mycobacterium still present will be re-probed at 2 months and every month it is still positive. If the client is not improving consider the development of resistance, poor absorption of drugs or client not taking drugs. Consult with TB Program.

k. Consult the TB Control Program for information regarding the treatment of clients if they are:

- Drug resistant
- Children
- HIV positive
- Pregnant

l. The basic principles that underlie the treatment of pulmonary tuberculosis also apply

to extra pulmonary forms of the disease. Thus, a 6 month course of therapy is recommended for treating tuberculosis involving any site with exception of 6-9 month for bone joint and 9-12 for CNS.

m. First Line TB Drug Monitoring and Adverse Reactions

Drug	Adverse Reactions	Monitoring	Comments
Isoniazid	Hepatic enzyme elevation Hepatitis Hypersensitivity reactions Peripheral neuropathy Mild effects on central nervous system Lupus-like syndrome Monoamine poisoning	Baseline and monthly hepatic enzymes for adults Repeat measurements if baseline is abnormal, if high risk for adverse reactions, if symptoms of adverse reactions	Hepatitis risk increases with age and alcohol consumption Pyridoxine can usually prevent peripheral neuropathy *see ATS/CDC/IDSA Treatment of Tuberculosis, 2003, section 7.2.2 for drug interactions.
Rifampin	GI upset Orange discoloration of body fluids Hepatitis Immunologic reactions Flu-like symptoms Rash	Baseline CBC, platelets, and hepatic enzymes for adults Repeat if baseline abnormal or if symptoms of adverse reactions	Significant interactions with methadone, birth control pills, and other drugs Colors body fluids orange May permanently discolor soft contact lenses *see ATS/CDC/IDSA Treatment of Tuberculosis, 2003, section 7.2.1 for drug interactions
Pyrazinamide	Hepatitis Rash GI upset Joint aches Hyperuricemia Gout	Baseline uric acid and hepatic enzymes for adults Repeat if baseline abnormal or if symptoms of adverse reactions	Treat hyperuricemia only if client has symptoms Little information about the safety during pregnancy
Ethambutol	Optic neuritis Cutaneous reactions	Baseline and monthly tests of visual acuity and color vision	Not recommended for children too young to be monitored for changes in vision unless TB is drug resistant

n. Rifampin may decrease the effectiveness of oral contraceptives; as well as interact with multiple other medications. An alternative method of birth control should be used for 60 days after discontinuation of the drug. See ATS Guidelines for common drug interactions.

o. All clients with ATBD should be offered HIV counseling and testing. In the presence of HIV infection, it is critically important to assess the clinical and bacteriological response. TB treatment regimens may need to be altered for HIV-positive clients taking protease inhibitors. Because of the complexity of management of TB in the HIV positive client, it is **strongly recommended that consultation with an expert in the management of both TB and HIV disease be considered**. See TB/HIV drug interactions.

p. Careful attention should be given to measures that foster adherence to therapy (e.g., incentives and enablers). See section on Incentives and Enablers in this manual or consult with the TB Control program for assistance with incentives and enablers. Intermittent therapy regimens are available for select clients. Consult the TB Control Program for more information.

q. A case manager should be assigned to ensure that clients receive appropriate monitoring, complete treatment, and contacts are examined. See section on Contact Investigation for more details.

r. When therapy is interrupted see ATS/CDC/IDSA Treatment of Tuberculosis, 2003 section 5.7 for recommendations.

s. A full course of therapy is determined more accurately by the total number of doses taken, not solely by the duration of therapy. (see ATS/CEC/IDSA Treatment of Tuberculosis, 2003 Table 2)

t. For pulmonary ATBD, a chest x-ray and sputum should be done at the completion of treatment.

u. Follow-up of ATBD should be done at scheduled intervals. (See section on post-treatment evaluation)

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition, 2000. (Page 65-79)

American Thoracic Society Diagnostic Standards and Classification of Tuberculosis in Adults and Children, September 1999. (Page 1360-1370)

American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America: Treatment of Tuberculosis 2003

Follow-up Responsibility

TB Nurse Consultant
Utah State Pulmonary Consultants

Contact Investigation

Purpose

To establish a policy for determining when a contact investigation needs to be initiated, how to prioritize and evaluate contacts, recommended treatment and follow-up of contacts and when to expand the investigation.

Policy

Contact investigation is an integral part of the TB Control Program and one of the best ways to find people who have active TB disease (ATBD). The purpose of the investigation is to find contacts who (1) have ATBD so that they can be given treatment and further transmission can be stopped, (2) have latent TB infection (LTBI) so they can be given treatment, and (3) are at high risk of developing ATBD and therefore require treatment until LTBI can be excluded. Each local health department is legally responsible for ensuring that a complete and timely contact investigation is done for TB cases and highly suspect TB cases reported in its area.

Procedure:

a. Identify: Who is a Contact?

Contacts are persons exposed to someone with infectious TB disease. Exposure to TB is time spent with or near such a person and is determined by the duration, proximity, and intensity of the shared time. Contacts generally include family members, roommates or housemates, close friends, coworkers, classmates, and others. Public health agency staff usually identify contacts by interviewing the person with ATBD and by visiting the places where that person spends time regularly.

b. Identify: When is a Contact Investigation Done?

A contact investigation is a systematic procedure for tracing, testing, and evaluating persons who have been exposed to someone with infectious TB. **In general, a contact investigation should be done whenever a client is found to have or is suspected of having infectious pulmonary or laryngeal TB disease (e.g. symptoms and chest x-ray consistent with TB disease) and should commence no more than 3 working days after the case is reported.**

Infectiousness depends on a variety of factors, but is more likely when clients have:

- Hoarseness
- Other symptoms of pulmonary or laryngeal TB
- Positive sputum AFB smear or culture results for *Mycobacterium tuberculosis* complex (MTB). Recent evidence suggests that transmission can occur in sputum AFB smear-negative cases as well
- Cavity on chest x-ray
- Inadequate or no treatment

Young children with pulmonary TB disease are rarely infectious, so a contact investigation is generally not conducted for them. Instead a **source case investigation** (looking for the source of exposure) is done. However, young children with ATBD should be evaluated for infectiousness and contact investigation may be warranted in some circumstances.

A source case investigation is usually done when:

- A young child is found to have TB disease
- A severely immunocompromised person who does not have a known history of latent TB infection (LTBI) is found to have ATBD
- A cluster of TST conversions is found in a high-risk institution (e.g. health care or correctional facility)

A source case investigation is conducted to determine who transmitted TB to the child, index patient or persons in the cluster of skin test conversions, whether this person is still infectious, whether this person was reported to the health department or if others were infected by the same source patient. The TB Control Program requires a source case investigation be completed when ATBD is identified in a child under the age of four.

Supervisory clinical and management staff should make decisions regarding prioritization of contact investigations. Setting priorities between two or more contact investigations is a decision that should be made based on the likelihood of infectiousness of the index case:

- Positive sputum AFB smear
- Positive culture
- Extra-pulmonary TB

If program resources are limited, priority should be given to contacts that were exposed to the most infectious TB clients or to those who are at highest risk for progressing to disease, if infected. The TB Control Program **DOES NOT PAY** for testing or follow-up for non-contacts (persons who have not shared time or were not near a person with infectious TB).

c. Steps in a Contact Investigation

A successful contact investigation requires careful gathering and evaluation of detailed information, often involving many people. In general, contact investigations follow a process that includes these basic steps:

Medical Record Review

Review of the TB client's medical record and information from the clinician to determine whether the client has been infectious and, if so, for how long. Knowing when the client was infectious helps to determine which contacts are at risk. In general, count back 2-3 months prior to the time the client reports symptoms.

Client Interview (TB Case Interview)

The client interview is one of the most critical parts of the contact investigation. If the interviewer does not communicate well enough with the client to get accurate information about symptoms, places where the client spent time, and contacts, people who need evaluation and treatment may be missed. The interviewer should keep in mind that if the client first learns of their new TB diagnosis during the initial interview they may be overwhelmed. Thus, **follow-up interviews should be scheduled to educate clients and to complete a thorough contact investigation**. Good communication (asking open-ended questions), good listening skills, client education, and establishing and maintaining a trusting relationship are essential during all interviews.

The initial interview should occur **no more than 3 working days** after the case is reported for sputum AFB smear positive cases/suspects with a high index of suspicion for TB. During the interview, the TB client should be asked more about:

- Symptoms – type and onset; especially cough and sputum production
- Places where the client spent time while he/she was infectious (e.g. household – including guests and visitors, work, school, leisure, recreation, transportation, incarceration, travel, medical/dental or beauty appointments)
- Any contacts
- How often and how long the contacts were exposed
- Locating information for the contacts

Some clients may be reluctant to identify some or all of the contacts. For example, a client may not want to identify people who use illegal drugs with him/her. The interviewer should be sensitive to the client's fears, explain the importance of testing

the contacts, and **assure the client that all information will be kept confidential (including the client's name).**

Field Investigation

A field investigation means visiting the TB client's home or shelter, workplace (if any), and other places where the client said he/she spent time while infectious to identify contacts and evaluate the environmental characteristics of the places were exposure occurred. The public health worker should assess for:

- Room size
- Crowding
- Ventilation
- Contacts (especially children) and their locating information
- Evidence of other contacts who may not be present (e.g. pictures of others who may live in the place, shoes left by others who may live in the house, maintenance/ cleaning workers in the home, toys left by children)

Close contacts that are present should 1) receive a tuberculin skin test (TST) and arrange for reading of the results; 2) be educated about the purpose of the investigation, basic TB transmission, risk of transmitting TB to others, and importance of testing, treatment, and follow-up for LTBI and ATBD; and 3) be referred for medical evaluation, including chest x-ray and sputum collection if they have symptoms of TB.

Risk Assessment for MTB Transmission

The infectiousness of the TB client is dependent upon the duration of time when the client was infectious and estimated degree of infectiousness. The degree of infectiousness is estimated from information regarding the client's symptoms, sputum smear results, and other conditions identified during the medical record review and client interview. The greater degree of infectiousness, the more likely transmission will occur.

The risk of transmission in a particular space depends on the concentration of infectious droplet nuclei in the air. Small room size, crowded conditions, poor ventilation and lack of air cleaning systems increase the risk of transmission of MTB.

The length and closeness of exposure between the TB client and a particular contact are key factors in assessing the contact's risk. Persons who frequently spend a lot of time with the TB client or have been physically close to the client are at higher risk of becoming infected.

Finally it must be considered, regardless of the length of exposure, if the contacts are at a high risk of developing TB disease if infected.

Prioritization of Contacts

To use time and resources wisely, the contact investigation should be focused on the high-priority contacts (contacts who are at greatest risk for developing TB infection or disease).

These **high-priority contacts** include:

- Close Contacts—most likely to be infected based on risk assessment information (close, regular, prolonged contact with the TB client while he/she was infectious, especially in small, poorly ventilated places). Not limited to household contacts.
- High Risk Contacts—contacts who are at high risk of developing TB, once infected (e.g. children less than 4 years of age, HIV-infected or other immunocompromised persons, and persons with certain medical conditions).

Contacts with less intense, less frequent or shorter durations of contact to the TB client are classified as **lower-priority contacts** and should only be evaluated if it is determined that the contacts need to be expanded.

Evaluation of Contacts

Evaluation of TB contacts includes at least a medical history and TST. **Close contacts and high-risk contacts should be examined first.** Contacts should be offered HIV counseling and testing. Contacts should be asked about their history or treatment of previous TB infection or disease, documented previous TST results, previous exposure to TB, risk factors for developing TB disease, and current symptoms of TB. All high-priority contacts should be given a TST. **A reaction of 5mm or greater is considered positive for contacts.** Contacts with a positive reaction should be further evaluated for ATBD. Contacts who have a previously documented positive TST should not receive another test but should be evaluated for TB disease, including a review of symptoms and obtaining a chest x-ray.

Because it takes 2-8 weeks after TB infection for the body's immune system to react to tuberculin (window period), contacts who had a negative reaction on the initial TST should be retested 8 weeks after their last exposure to the infectious TB patient.

Infants under 6 months of age may have a false-negative TB skin test reaction because their immune systems are not yet able to react to tuberculin. Thus, infants need careful clinical evaluation.

Contacts who have TB symptoms, are HIV-infected, have other immunosuppressive conditions or are under 4 years of age should have a chest x-ray at the same time as the initial skin test to evaluate him/her for TB disease. This is because of their high risk of quickly developing TB disease. In addition, these close contacts should be considered for treatment of LTBI (once ATBD is ruled out) even if the initial skin test reaction is negative during the window period. Treatment may be discontinued if the 8 week follow-up skin test is still negative and the contact is not at continued risk for exposure to infectious TB.

Contacts who have an abnormal chest x-ray or symptoms of TB disease should have three early-morning sputum specimens, collected on three different days, for smear and culture examination, regardless of his/her TST reaction.

Results of all Contact Investigations should be documented on the UDOH CI Record and sent to TB Control Program at 30 days, 120 days and at completion of treatment for LTBI.

Treatment and follow-up for contacts

The following contacts should be offered treatment for LTBI:

- Contacts with a positive TB skin test reaction and no evidence of TB disease
- High-risk contacts who have a negative TB skin test reaction who may develop TB disease quickly after infection (e.g. children under 4 years of age, HIV-infected persons, other high-risk contacts)

Contacts recently infected with TB are high-priority for treatment of LTBI because they are at high-risk of developing ATBD (highest risk of developing ATBD is in the first 2 years after infection). HIV-infected contacts or other immunosuppressed contacts may be given a full course of treatment for LTBI, regardless of their TST results, because of the possibility of a false-negative skin test result (inability to react to tuberculin due to a compromised immune system).

Contacts who have a positive sputum smear or chest x-ray result suggestive of current TB disease should begin treatment for ATBD.

Contacts who have started treatment for LTBI or ATBD should be monitored to ensure compliance and completion of treatment. Contacts with LTBI who have a high-risk for progressing to ATBD or who are at a risk for non-adherance should be considered for directly observed therapy (DOT) when possible (e.g. children, HIV positive or immunosuppressed clients, homeless clients and substance abuse clients)

Decision About Whether to Expand Testing

After the highest priority contact group has been evaluated for LTBI and ATBD, the contact investigation staff should evaluate the results of testing for evidence of recent transmission. Evidence of recent transmission is indicated by any of the following factors:

- High infection rate among contacts as compared to the local community positivity rate
- Infection in a young child
- A TST conversion in a contact
- A secondary case of ATBD

To calculate the infection rate among a given group of contacts:

- Determine the number of contacts with newly-identified positive skin tests
- Determine the total number of contacts without a documented previous positive skin test. Subtract the number of contacts with a documented previous positive skin test from the total number of contacts.
- Determine the infection rate. Divide the number of contacts with a new positive skin test by the total number of contacts without a documented previous positive skin test. Multiply by 100; the resulting percentage is the infection rate for the group of contacts.
- Compare the level of skin test positivity rate in the local community (based on TB Control Program estimates) to the infection rate for the group of contacts.

When there is evidence of recent transmission of TB in the first group of close contacts tested, the likelihood that TB has also been transmitted to contacts with less exposure increases. The testing should, therefore, be expanded to these contacts ("concentric circle approach"—see References, "Contact Investigations for Tuberculosis. Self Study Module 6, October 1999"). This should be done as soon as it becomes clear that transmission may have occurred. The decision about expanding contact investigation to the next group of contacts should be made by clinical and supervisory staff, based on an assessment of all available information.

On the other hand, if there is NO evidence of recent MTB transmission among close contacts, testing should not be expanded to the next group of contacts (e.g. new positive skin test rate among contacts is lower than or similar to the level of infection in the community, no young children have a positive skin test reaction, no contact skin test conversions have occurred, no contacts have TB disease). Once the infection rate among the group being tested is the same as the infection rate in the local community and there are no other factors indicating recent transmission, testing can be stopped.

Evaluation of Contact Investigation Activities

An evaluation of the contact investigation activities should be conducted with or by a supervisor to determine such things as:

- Were appropriate number of contacts identified?
- Were the highest-priority contacts located and tested?
- ¨ Was the contact investigation performed in all settings: household or residence, work or school, and leisure or recreational environments?
- ¨ Was the contact investigation expanded appropriately? Were contacts completely evaluated (including second skin test if needed) and given appropriate therapy if they had TB infection or disease?
- ¨ How many infected contacts completed a regimen of treatment for LTBI?
- ¨ Did all identified cases complete an adequate treatment regimen?

The answer to these questions will help determine how successful the contact investigation has been.

Results of all TB contact investigation activities should be documented on the Contact Investigaion Record and submitted to the TB Control Program upon completion (including names and locating information for any out-of-state contacts identified). The information will be compiled and evaluated by TB Control Program management staff as part of ongoing program evaluation activities.

References

Tuberculosis Nursing
Self-Study Modules on Tuberculosis: Contact Investigations for Tuberculosis, Centers for Disease Control and Prevention, October 1999 -
Contact Investigation Record under the forms section of the TB Control Web Site

Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC

Follow up Responsibility

TB Epidemiologist

Isolation Considerations

Purpose

To establish a policy for determining when a client with active TB disease (ATBD) needs to be isolated, quarantined or have restricted activity to reduce disease transmission.

Policy:

A client with ATBD will be considered infectious, and therefore capable of transmitting TB to others, when they have disease in the lungs, airways or larynx and have positive acid fast bacilli (AFB) sputum smears. Other factors that correlate with the contagiousness of an active case are the presence of cough, cavitation on chest radiograph, inappropriate or short duration of treatment, or poor clinical response to treatment. Transmission, although rare, has occurred with smear negative, culture positive clients.

Procedure

a. A client who is considered contagious should be given a mask to wear, instructed to remain at home, or evaluated for the need for hospitalization. The environment should be evaluated for high-risk contacts who may be at risk for developing disease.

b. Clients are to remain in isolation until they meet the following criteria:

- They are on adequate therapy for 2-3 weeks
- They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
- They have **three** negative AFB sputum smear results collected 8-24 hurs apart, with at least one being an early morning specimin.

c. Clients with extra-pulmonary TB usually are not infectious unless they have pulmonary or laryngeal TB in addition to their extrapulmonary disease or have an abscess or open lesion requiring treatment that may lead to aerosolization of wound drainage.

d. In general, children who have pulmonary TB are less likely to spread TB than adults because children do not usually develop a cough strong enough to aerosolize TB organisms. However, transmission from children can occur in certain situations.

Therefore, children with TB should be evaluated for infectiousness using the same factors as above for adults.

e. If a client fails to adhere to isolation and is considered a public health risk, consult the TB Control Program, and refer to Section on Quarantine and Isolation of Non-adherent Clients with Tuberculosis in section two.

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000. (Page 88)

Utah Department of Health TB Program Quarantine Manual

Follow-up Responsibility

TB Nurse Consultant

Transmission Prevention & Infection Control Planning

Purpose

To establish a policy for the community to prevent the transmission of tuberculosis through an effective infection control plan.

Policy

In accordance with federal and state law, an effective TB infection control program must be implemented by all health care facilities, ambulatory-care settings, emergency departments, and other health care settings. The extent of the TB infection control program should be based on a risk assessment for transmission of *M. tuberculosis* and appropriate control measures to minimize that risk in a given setting.

Procedure

a. Personnel should be assigned to perform an assessment of the risk for transmission of TB in a particular setting, area or occupational group based on:

- The profile of TB in the community
- The number of infectious TB clients admitted to the area or ward, or the estimated number of infectious TB clients to whom health care workers (HCWs) in an occupational group may be exposed
- The results of analysis of HCW skin test conversions (where applicable) and possible person-to-person transmission of MTB

b. **Administrative controls** to reduce the risk of exposure to persons with infectious TB should include:

- Developing and implementing effective written policies and work practices to ensure the rapid identification, isolation, diagnostic evaluation, and treatment of persons likely to have ATBD
- Implementing effective work practices among health care workers in the health care facility

c. Written TB infection Control protocols must be developed to include:

- Triage to promptly identify clients who may have TB
- Promptly evaluate clients who have TB symptoms
- Place client in a separate area apart from other clients and not in open waiting areas (ideally in a room or enclosure with special ventilation maintained under negative pressure)

- Give client a surgical mask to wear until he/she can be transported to an appropriate isolation room or until he/she leaves the building
- Give the client a tissue and instruct them to cover their mouth and nose when coughing or sneezing
- Schedule appointments to avoid exposing other clients, especially HIV infected or immunocompromised persons
- Avoid performing a cough-inducting procedure (e.g., sputum inductions) on clients who may be infectious unless the procedure is absolutely necessary and performed using local exhaust ventilation devices such as booths or special enclosures or in a room that meets ventilation requirements for TB isolation
- Allow enough time to pass for at least 99% of airborne contaminants to be removed before placing another client in a room or area previously occupied by an infectious client (Consult the manufacturers operating instructions or a qualified engineer to define the length of time needed to remove at least 99% of airborne contaminants)
- If the client is placed in TB isolation and is not wearing a mask, all persons entering the room must wear respiratory protection which meets minimum requirements for TB transmission prevention
- TB transmission prevention precautions can be discontinued if the diagnosis of TB is ruled out or if contagiousness is ruled out
- Visitors must wear an appropriate respirator and be instructed how to wear it

d. Personnel must be educated and trained, as appropriate for their work responsibilities and duties, regarding tuberculosis. Training should occur before initial assignment, and the need for additional training re-evaluated periodically. Education should include: TB transmission, pathogenesis, diagnosis, difference between therapy for latent TB infection and disease, signs and symptoms of TB, higher risks of disease associated with immunocompromised persons, prevalence of TB in the community and facility, transmission prevention precautions, situations that increase risk for exposure, purpose of tuberculin skin test (TST), significance of a positive TST result and recommended follow-up, disease reporting procedures (including symptoms in health care workers), confidentiality, information regarding BCG vaccine associated with principles of TST, and options for work reassignments for immunocompromised HCWs.

e. Personnel must be counseled and screened for TB and TB infection, which includes developing and implementing a tuberculin skin testing program for persons in the facility with the potential for exposure to TB. HCWs, including home health nurses, clinic workers and emergency medical technicians, should be included in a TST and prevention program if the risk assessment indicates that they are at risk for exposure. This means TST upon employment **using the two-step method** and at repeated intervals determined by their risk of exposure thereafter. Any worker who develops symptoms of TB disease or whose TST result converts to positive should be evaluated promptly and reported to the TB Control Program.

f. **Engineering controls** to prevent the spread and reduce the concentration of infectious droplet nuclei in the air, include:

- Ventilation systems to maintain negative pressure and exhaust air properly in TB isolation rooms.
- HEPA filtration and ultraviolet irradiation in high risk areas.

g. A respiratory protection program for personnel must include: The selection of **NIOSH-approved particulate respiratory protection** which meets the minimum requirements for TB transmission prevention, medical evaluation and fit testing, training in the use and maintenance of respirators, and program evaluation.

h. Facilities that admit TB patients, must initiate isolation in a private isolation room with special ventilation maintained under negative pressure relative to other parts of the facility. The room must be monitored daily while in use to assure that appropriate ventilation is maintained, the door must remain closed, and the client should only leave the room for medically essential purposes. For the safety of all workers and visitors, the isolation room must be clearly identified as housing a potentially infectious patient. When the client must leave the room, the patient should wear a surgical mask that covers the nose and mouth at all times. Clients who are placed in isolation rooms should be educated about the transmission of TB, the reasons for isolation, and the importance of staying in their rooms. The client should also be instructed to cover their nose and mouth when coughing, or sneezing.

The number of persons entering the room should be limited and those entering the room must wear appropriate personal respiratory protective devices. These devices must adequately fit the worker or visitor and be "user seal" checked" before use. **Clients evaluated or admitted to an inpatient facility and determined to have suspected or known active TB disease (ATBD) which is infectious cannot be released until the state or local health agency has made arrangements for appropriate isolation/ quarantine post discharge.** They are considered noninfectious when meet all of the following criteria:

- They are on adequate therapy for 2-3 weeks
- They have significant **clinical response to therapy** (i.e., reduction in cough, resolution of fever)
- They have **three** negative AFB sputum smear results collected 8-24 hurs apart, with at least one being an early morning specimin.

- Proper isolation procedures must be maintained while at the facility. Isolation should only be discontinued when it is determined that the patient is no longer contagious. Settings/facilities unable to adequately evaluate patients who have, or are suspected to have, infectious TB should develop a triage system to identify, manage and refer these patients to another facility for diagnostic evaluation and treatment.

i. Some clients with suspected or known ATBD may be evaluated or treated in an outpatient setting under the supervision of or directly provided by the local public health agency.

j. All ambulatory-care settings and emergency departments must develop, implement, and update a TB infection control plan in accordance with federal and state rules and/or recommendations as outlined above.

k. Contact the TB Control Program for consultation regarding the appropriateness of home placement for individual clients. Clients who are placed at home should be instructed to cover their nose and mouth when coughing or sneezing and be instructed on the importance of taking prescribed therapy and directly observed therapy (DOT). Health care workers or visitors must wear appropriate respiratory protection when visiting clients with confirmed or suspect infectiousTB. Avoid performing cough-inducting procedures on clients who are infectious or use appropriate respiratory protection and perform in a well-ventilated area.

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000. (Pages 87-95)

Centers for Disease Control Guidelines for Preventing transmission of TB in Health Care Facilities, 2005

Follow Up Responsibility

TB Epidemiologist

Improving Adherence with Therapy

Purpose

To establish a policy for improving compliance with therapy for clients with latent TB infection (LTBI) or active TB disease (ATBD).

Policy

Adherence to medication regimens for tuberculosis is a priority and can be accomplished through the use of Directly Observed Therapy (DOT), incentives and enablers. DOT is considered the standard of care for clients with ATBD and is recommended for use with high-risk clients with LTBI. The responsibility for successful treatment is clearly assigned to the public health program or private provider not to the client.

Procedure

a. **Directly Observed Therapy (DOT)** is the standard method of providing treatment to all persons with ATBD. Many health care providers believe they can predict whether a particular client will take medication as prescribed. However, research data indicate that providers, on the average, are correct only 50% of the time. In addition, DOT allows for the immediate detection of non-compliance so that actions can be taken to avoid treatment failure.

b. Health care providers must recognize that even with DOT, additional strategies and efforts are necessary for treatment success. It is important to use any tool available in order to promote adherence to therapy.

c. Consider entering into a “contract” with the client which clearly states the clients responsibilities in regards to treatment.

d. Learn as much as possible about your client’s health history, beliefs and attitudes about TB, sources of social support, and potential barriers to treatment prior to starting treatment.

e. Work with a medical interpreter or a person of the same cultural background as the client, if possible.

f. Designate a person to do DOT who does not have strong emotional ties with the client. Suitable designees might include school nurse/staff, employee health, public health, or visiting nurse, clergy, or other responsible person. Family members are not the appropriate choice to assist because of power struggles and family dynamics.

g. Mutually agree on a time and location for DOT, be creative and flexible.

h. Be aware of clients who may require techniques to assess for complete ingestion of medication (e.g., hiding pills in mouth, vomiting after pills swallowed).

i. Use incentives and enablers to assist in improving compliance. The TB Control Program can assist with rent, food coupons, payment of limited bills, and rewards for specific milestones in treatment. Housing is available in some communities. Specific incentives are available to assist young children and contacts to cases of active TB Disease to complete treatment for LTBI. Contact the TB Control Program for more information on the use of incentives and enablers.

j. Look for early warning signs of future adherence problems (e.g., client feels medicine is no longer needed because they are feeling well, difficulty in accessing health care, transportation issues, worksite concerns, etc.). See Procedure for Managing Persons at Risk to Be Lost to Treatment under forms section.

k. Provide effective education to clients and key individuals in their environment.

l. Provide client with needed health or social services or make referral to other health or social service agencies.

m. Use a team of personnel whose members work together to assist each client in completing treatment.

n. Establish an efficient, client-friendly clinic system for scheduling appointments, keeping records, and monitoring adherence

o. If, despite your best efforts, the client does not adhere to DOT voluntarily, Utah State statutes allow court-ordered isolation/quarantine. See next section on Quarantine or Quarantine Manual. Contact TB Control Program for more information and assistance.

References

Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition 2000.

Incentives and Enablers, Division of Tuberculosis Control, South Carolina Department of Health and Environmental Control

ATS/CDC/IDSA Treatment of Tuberculosis, 2003

CDC Self Study Module on TB, Module 9 Patient Adherence to TB Treatment

Follow Up Responsibility

TB Nurse Consultant

Quarantine, and Isolation of Non-Adherent Clients with ATBD

Purpose

To establish a policy for use of quarantine and isolation with non-adherent clients with tuberculosis.

Policy **(UNDER CONSRUCTION)**

In partnership with the local health departments (LHDs) and health care providers, the Utah Department of Health is responsible for implementation of the Utah Administrative code, Title 26, Chapter 6b, Communicable Diseases Treatment, Isolation, and Quarantine Procedures. This statute delineates the process for ordering involuntary treatment, isolation, and quarantine of persons with public endangering communicable diseases who are unable or unwilling to fully participate in their prescribed treatment.

Procedure

a. Within the context of tuberculosis disease, the first priority of public health is to prevent further transmission of tuberculosis in the community by an infectious individual. This is accomplished by identifying all persons with active TB disease (ATBD) and ensuring appropriately prescribed treatment is completed. **In order to safeguard appropriate use of scarce resources and comply with the civil liberty rights of the individual, it is recommended that the less restrictive levels of care be pursued aggressively before progressing to more restrictive levels.**

The levels of care are:

- **Level of Care 1**: Prescribed outpatient treatment, including directly observed therapy (DOT), provided by a health care provider, clinic, or LHD for those individuals both willing and able to fully participate in the treatment of their active tuberculosis disease.
- **Level of Care 2**: Enhanced provision of outpatient treatment with use of incentives, enablers, directly observed therapy (DOT), electronic surveillance, etc., for individuals who indicate an unwillingness or inability to undergo prescribed medical treatment, or have demonstrated poor adherence to treatment that has been previously initiated. Implementation of these additional measures ensures completion of treatment.
- **Level of Care 3:** Secure/locked housing such as long-term care settings, for those persons who have not responded to Level 2 strategies and are non-infectious. Adequate measures are provided that minimize/eliminate the flight risk of these

individuals (this measure is currently not available in Utah).

- **Level of Care 4**: Secure/locked hospital unit or facility offering negative pressure isolation and staff trained in tuberculosis control for accommodating clients with ATBD who have failed adherence to treatment at less restrictive levels of care.

b. The Advisory Council for the Elimination of Tuberculosis defines non-adherent behavior as the inability or unwillingness to follow a prescribed treatment regimen. This may be demonstrated by refusing medication, taking medication inconsistently, missing healthcare provider appointments, failing to report for DOT. Individuals appropriate for court-ordered evaluation may also include contacts of active TB cases who are flight risks.

c. Although many health care providers believe they can predict a client's adherence to treatment, research indicates their predictions are correct only about 50% of the time. **The strongest predictor of adherence to treatment is the client's history of adherence. The strongest predictor of future adherence problems is a history of nonadherence to treatment, particularly with TB medications.** If there is documentation of nonadherence with previous TB treatment or therapy for LTBI, it is unlikely that the client will be successful in adhering to the current treatment regimen.

d. Other indicators for high-risk of nonadherence include: history of other medical treatment nonadherence; substance abuse; mental, emotional, or certain physical impairments that interfere with the ability to self-administer medications; children and adolescents. It is recommended that health care providers formally evaluate each client's potential nonadherence at the time TB medication is prescribed. The issue of treatment adherence is addressed in detail in the publication Improving Patient Adherence to Tuberculosis Treatment, U.S. Department of Health and Human Services and Centers for Diseae Control and Prevention (1994)

e. If nonadherence with prescribed TB medications is a concern, contact the TB Control Program to discuss prior to initiating any quarantine/isolation procedures. Documentation of nonadherence is essential to success with this process.

f. Quarantine Manual:

References

Utah Department of Health, Quarantine Manual.

Improving Patient Adherence to Tuberculosis Treatment, U.S. Department of Health and Human Services and Centers for Diseae Control and Prevention (1994)

Procedure for Managing Persons with Suspected or Confirmed Active TB Disease Who are at Risk to be Lost to Follow Up or Who Become Lost to Treatment

Follow up Responsibility

TB Control Program Manager

Utah State Health Laboratory/ Mycobacteriology Laboratory

Purpose

The Utah State Health Laboratory tests for the presence of acid-fast bacilli (AFB) in clinical specimens submitted by private health care providers and public agencies. The laboratory also determines the identification of AFB species and performs susceptibility testing on *Mycobacterium tuberculosis* complex. Private laboratories also refer isolates to the laboratory for identification and susceptibility testing. With the exception of blood cultures for AFB, these services are provided at no charge.

Policy

Submitting Specimens

Specimens should be delivered to the Utah State Health Laboratory at 46 N. Medical Drive, Salt Lake City, Utah either by courier or U.S. mail as soon as possible after collection. See Specimen Collection and Transport for detailed instructions.

Testing Schedule

Specimens are processed once a day, Monday through Saturday for AFB culture. Specimens that are received in the laboratory by 10:30 A.M. are included in that day's "run".

AFB smears from specimens processed Monday through Friday are generally read by 4:00 P.M. on the same day. AFB smears from specimens processed on Saturday are completed on the following Monday morning.

Identification and susceptibility testing is performed as required and completion of testing in some cases can take several weeks.

If a patient is still producing positive cultures after two months treatment, the isolate will be identified to determine if it is *M. tuberculosis*. If the isolate is *M. tuberculosis* the susceptibility testing will be repeated.

Procedure

Testing Methods

AFB smears are stained using the Auramine O method and examined using fluorescent microscopy.

Specimens that are likely contaminated with other bacteria are processed using the NALC-NaOH method and inoculated to 7H11 solid medium and to BACTEC MGIT broth medium.

Specimens from sterile sites are inoculated directly to 7H11 solid medium and to BACTEC MGIT broth medium.

Blood and bone marrow specimens are inoculated to BACTEC Myco/F-Lytic broth.

Identification is determined by Accuprobe DNA probe, HPLC, and conventional biochemical testing.

Susceptibility testing is performed using the BACTEC MIGIT 960.

Reporting Schedule

AFB reports are made to the requesting provider by the method they have specified. This can be by U.S. mail, fax, or E-mail.

AFB smear results are generally reported at 4:00 P.M. on the day they are processed.

Positive cultures are reported as they are found and identification and susceptibility results are reported as the testing is completed.

Negative cultures are held for a minimum of six weeks. Final “no growth” cultures are reported once a week.

DNA Genotyping of *Mycobacterium tuberculosis*

DNA genotyping of *M. tuberculosis* is a useful epidemiological tool that can be used to detect possible outbreaks, track the transmission of tuberculosis in the population or obtain evidence that cross contamination has occurred in the laboratory. The Centers for Disease Control and Prevention has contracted with several Public Health laboratories to provide this service to the states.

The initial isolate from each new Utah patient found to have *M. tuberculosis* complex in specimens submitted to the State Health Laboratory will be sent to a CDC contract laboratory for DNA genotyping. Other laboratories performing AFB testing on Utah residents are requested to send isolates of *M. tuberculosis* to the State Health laboratory, which will then submit them for genotyping.

There are cases where additional isolates may be submitted. Patients whose isolates have become resistant and patients who have become negative on culture and then have reverted to positive will have the second isolate submitted to determine if the patient has become infected with a new strain. The TB program may also request additional submission of isolates when they feel it is appropriate.

References

Guide to the Application of Genotyping to Tuberculosis Prevention and Control http://web-tb.forum.cdc.gov

Murray et al. 2003. Manual of Clinical Microbiology, 8th ed. American Society of Microbiology, Washington DC.

Public Health Mycobacteriology, A Guide for the Level III Laboratory, Centers for Disease Control. 1985

Laboratory Contacts

The following contacts can all be reached through the main laboratory phone number, (801) 584-8400.

Barbara Jepson, MPA, MT(ASCP)
Director, Bureau of Microbiology

Dan Andrews, MS, MT(ASCP)
Section Chief, Bacteriology/Mycobacteriology Laboratory

Robyn Weaver, BS
Lead Microbiologist, Mycobacteriology Laboratory

Stephanie McGee
Microbiologist

Chris Peper, BS, MT(ASCP)
Section Chief, Technical Services

Utah State Laboratory
Specimen Collection and Transport

Purpose

To establish a policy for collection and transportation of specimens submitted for mycobacterial culture.

Policy

The Utah Department of Health (UDOH) State Laboratory tests a variety of specimens for mycobacterial culture. These tests are provided at no charge to local health departments and health care providers in the state of Utah. The quality of the specimens collected and proper transport of those specimens to the laboratory are critical to the successful isolation of AFB (acid-fast bacilli).

Procedure

a. Specimens should be collected and submitted in sterile, leak proof, disposable, appropriately labeled, laboratory-approved containers. **Label sputa collection container before giving to the client or collecting specimen.** All specimens can be collected in the sterile collection tubes supplied by the Utah Department of Health State Laboratory. Do not use waxed containers, as they may provide false-positive smear results.

b. Initial specimens should ideally be collected prior to the initiation of anti-mycobacterial chemotherapy. Specimens should be collected aseptically, or the collection method should bypass areas of contamination as much as possible in order to minimize contamination with indigenous flora. Avoid contamination with tap water or other fluids that may contain either viable or nonviable environmental mycobacteria, since saprophytic mycobacteria may produce false-positive culture and/or smear results.

c. Sputum: Sputum, both expectorated and induced, is the principal specimen obtained for the diagnosis of pulmonary tuberculosis. Collect an early-morning specimen, preferably 5-10 ml, from a deep, productive cough on at least 3 consecutive days (24 or more hours apart). It is recommended that dentures, if present, be removed before collection of sputum specimens. If the specimen is not an early morning sample, or if the client has eaten or used tobacco, rinse mouth with water. For expectorated sputum, clients should be instructed to cough deeply to produce specimens distinct from saliva, or nasopharyngeal discharge. The client should be instructed to press the rim of the container under the lower lip at the time of expectoration to minimize the chance of

contaminating the outside of the container. For induced sputum, use sterile hypertonic saline, and avoid sputum contamination with nebulizer reservoir water to avoid possible false-positive culture or smear results due to saprophytic mycobacteria. Indicate on the requisition whether the specimen is induced or expectorated to ensure proper handling, as induced sputa appear watery and much like saliva. Pooled sputum specimens are unacceptable specimens for mycobacterial culture because of increased risk of contamination.

d. Bronchoalveolar Lavage Fluids and Bronchial Washing: Bronchial washings, bronchoalveolar lavage fluid, transbronchial biopsy specimens, and brush biopsy specimens may all be collected during bronchoscopy. Collect at least 5 ml of bronchial washing or bronchoalveolar lavage fluid in a sterile container. Avoid contaminating the bronchoscope with tap water. Frequently, bronchoscopy causes the client to produce sputum spontaneously for several days after the procedure, and specimens collected a day or two after bronchoscopy enhance detection of mycobacteria.

e. Gastric Lavage Fluids: Aspiration of swallowed sputum from the stomach by gastric lavage may be necessary for infants, young children and the obtunded. On each of 3 consecutive days, collect 5-10 ml of fluid in a sterile container without a preservative. Fasting, early-morning specimens are recommended in order to obtain sputum swallowed during sleep. Gastric contents are initially collected with a sterile suction syringe connected to a tube inserted in the stomach. Sterile saline (20-30 ml) may then be induced into the stomach and aspirated as lavage fluid. The gastric contents and lavage fluid may be pooled in a sterile container. These specimens should be processed within 4 hours. If the specimens cannot be processed within 4 hours, adjust fluid to neutral pH with 100mg of sodium carbonate immediately following collection. Unneutralized specimens are not acceptable, as acid is detrimental to the mycobacteria.

f. Blood: Cultures for the isolation of mycobacteria from blood are usually reserved for the immunocompromised clients. The BACTEC Myco/F-Lytic bottle is specifically designed for the recovery of mycobacteria from blood. The Myco/F-Lytic medium can be directly inoculated with 5ml of blood. If blood needs to be transported before inoculation of BACTEC medium, use sodium polyanetholsulfonate (SPS) or heparin as an anticoagulant. Blood collected in EDTA (purple top tube) or blood that is coagulated is not acceptable.

g. Urine: Collect the first morning specimens, either by catherization or midstream clean catch, into a sterile container on 3 consecutive days. Appropriate cleaning of genitalia should precede collection. Organisms accumulate in the bladder overnight, and the first morning void provides best results. Specimens collected at other times are dilute and thus not optimal. A minimum of 40 ml is usually required for culture.

h. Stools: Stool specimens (>1g) should be collected in sterile, wax-free, disposable clean containers or transferred from a bedpan or from plastic wrap stretched over the toilet bowl and sent directly to the laboratory.

i. Body Fluids: Body fluids (cerebrospinal (CSF), pleural, peritoneal, pericardial, etc.) are aseptically collected by aspiration or surgical procedures. Collect as much as possible (10-15ml minimum) in a sterile container or syringe with a luer tip cap. CSF culture requires at least 2 ml.

j. Tissues (Lymph Node, Skin, Other Biopsy Material): Aseptically collect at least 1g of tissue, if possible, into a sterile container without fixative or preservative. Do not immerse in saline or other fluid or wrap in gauze. For cutaneous ulcers, collect biopsy material from the periphery of the lesion. Specimens submitted in formalin are unacceptable.

k. Specimen Transport: All specimens should be refrigerated (except blood) prior to transport to the laboratory unless transport to the laboratory is anticipated within 1 hour of specimen collection. When shipping specimens:

- Make sure that the specimen is in the appropriate sterile specimen collection container.
- Seal the container and label appropriately.
- Place the sealed specimen container into a second shipping container. A test requisition form must accompany each specimen and is also placed in the second container.
  The test requisition forms can be obtained from the laboratory Technical Services group at: (801) 584-8400 or on the internet at: https://health.utah.gov/lab, click on “Microbiology Client Services Manual” under Bureau of Microbiology.
  If a test request form is obtained from the Internet it is essential that the proper provider code be entered in the appropriate field. This code determines where test results are sent. If you do not know your provider code, call the Technical Services group or the AFB laboratory at (801) 584-8400.
  Specimen Containers suitable for mailing clinical specimens in the U.S. mail can be obtained from the Technical Services group by calling (801) 584-8400. These containers are designed primarily for sputum specimens and have prepaid postage.

  Send specimens to:
  Utah Department of Health State Laboratory
  46 North Medical Drive
  Salt Lake City, Utah 84113

References

U.S. Department of Health and Human Services 1985: Public Health Mycobacteria: Guide for Level 3 Laboratory.

Follow up Responsibility

Dan Andrews, State Health Laboratory

Confidentiality in TB Control

Purpose

To establish a policy for maintaining confidentiality in Tuberculosis Control.

Policy

The Tuberculosis Control Program recognizes **confidentiality** is an essential issue in many different aspects of TB Control. All information pertaining to individual clients shall be maintained in strict confidentiality according to this written policy.

Health care workers need to be aware of their agency policies on confidentiality, as well as those that are relevant to client health care worker encounters. The collection, management, and sharing of data gathered on TB clients must be held in the strictest confidence.

Procedure

a. Tuberculosis Control Program employees must read and sign the Utah Department of Health, Bureau of Communicable Disease Control Client Confidentiality Policy upon hire and when updated.

b. The CDC Self Study Modules on Tuberculosis, Confidentiality in Tuberculosis Control provides in depth information, which is recommended for all health care workers in TB Control.

References

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, October 1999: Confidentiality in Tuberculosis Control.

Follow up responsibility

TB Nurse Consultant

Criteria for Hospitalization in Secure TB Unit at UUMC

Purpose

To provide a secured facility for court ordered, non-compliant TB clients; uninsured clients requiring hospitalization for active TB disease (ATBD); suspect or infectious homeless individuals, and those who pose a public health threat to contacts in their living environment.

Policy and Procedure

Individuals requesting admission to the University of Utah Hospitals and Clinics' (UUH&C) Secured TB Unit (STBU) must follow the STBU Protocol. Prior approval **MUST** be received from the Utah Department of Health, TB Control Program Manager or Nurse Consultant as well as the designated pulmonary physician at UUH&C before attempting to transport the client.

Rule out TB and TB clients must have funding for their UUH&C admission authorized by the TB Control Program. The TB Control Program will pay for admissions as the payor of last resort.

Non-compliant TB clients must be admitted to the STBU under court order. For details on the isolation process refer to the Utah Isolation/Quarantine Manual.

Clients are not to be sent to the emergency department or admitted through the emergency department, unless prior arrangements have been made.

References

Request for Admission to the University Hospitals and Clinics' Secured TB Unit (STBU) Protocol.
STBU Call List
Utah Isolation/Quarantine Manual.

Follow-up Responsibility

TB Control Program Manager

TB Nurse Consultant

Post Treatment Evaluation

Policy

The TB Control Program recommends periodic post treatment evaluation of clients with Active TB Disease. A chest x-ray, brief physical examination and signs and symptom review are recommended. Sputum samples should be collected if client is able to produce sputum.

Procedure

a. The TB Nurse Consultant will send a Post Treatment Evaluation form to the TB Nurse Case Manager at the recommended scheduled evaluation times.

b. The TB Case Manager will complete the form and return it to the TB Control Program.

c. The State TB Pulmonary Consultant is available for review of x-rays if local consultant or physician is not available. The TB Nurse Case Manager can arrange to take the client to Chest Clinic at Salt Lake Valley Health Department by calling 801-534-4600.

d. Recommended frequency of Post-Treatment Evaluation:

6, 12, & 24 months	If cultures remain positive at 2 months If cavitary disease If Rifamycin drug not in regimen
6 & 12 months	All other cases

e. A nursing assessment is recommended at 3 & 9 months.

References

ATS/CDC/IDSA Treatment of Tuberculosis 2003

New York City Bureau of Tuberculosis Control

Follow up

TB Nurse Consultant
State Pulmonologist

TB Evaluation for B1 & B2 Refugees/ Immigrants

Purpose

To establish a policy for follow up of refugees/immigrants whose overseas medical examination is consistent with findings for tuberculosis.

Policy

The Department of Homeland Security (DHS) and Citizenship and Immigraion Services (USCIS) requires an overseas examination of all immigrants and refugees over age 15 for tuberculosis. A chest x-ray is done to screen for active infectious tuberculosis disease. Refugees with abnormal chest x-rays suggestive of clinically active tuberculosis have sputum smear examinations to determine if they have infectious disease. Refugees/immigrants identified with active TB disease (ATBD) are started on treatment prior to departure for the United States. Once the refugee/immigrant is no longer contagious, U.S. resettlement can occur. Class B conditions indicate the need for the refugee/immigrant to follow-up in the United States usually having an abnormal chest x-ray but negative sputum smear. The TB Control Program considers Class B conditions as suspect active TB until the evaluation is complete. LHD's have 30 days to locate and evaluate Class B refugee/immigrants.

Procedure

a. USCIS sends Class B Report on Alien with Tuberculosis to the TB Control Program.

b. TB Control Program forwards this Class B report to the local health department (LHD) in whose district the refugee will reside and the Refugee Health Program for follow up. The Refugee Health Program will assist in locating the client and arranging for interpreting services if needed.

c. LHD completes evaluation for tuberculosis. If refugee/immigrant has ATBD, the TB Control Program will be notified and appropriate treatment begun.

d. The class B report evaluation is completed and sent back to the TB Control Program.

e. The TB Control Program forwards the completed report to the Division of Quarantine, Centers for Disease Control and Prevention and maintains a copy in the Class B refugee/immigrant files.

References

MMWR: Tuberculosis Among Foreign-Born Persons Entering the United States: December 28, 1990.

Follow up Responsibility

TB Program Health Representative
Refugee Health Program Health Program Specialist
TB Nurse Consultant

Alien (Alien #, Name, Address, Phone): **REFUGEE/ IMMIGRANT**
A___-___-___

Name

Address

City **State** **Zip** **Phone:**

Sex [ ] M [ ] F Date of Birth (Mo./Day/Yr):

[ ] Class B-1 - Tuberculosis clinically active, not infectious
[ ] Class B-2 - Tuberculosis, not clinically active, noninfectious

REPORT ON ALIEN WITH TUBERCULOSIS

LOCAL HEALTH OFFICER:

This person recently entered the United States and is referred to you because the X-ray shows findings consistent with tuberculosis, as indicated in the accompanying report of medical examination performed abroad. This person may not have received chemotherapy or chemoprophylaxis and is referred to you because you may wish to initiate preventative treatment. Your initial evaluation would be appreciated. Please check the appropriate boxes below and return this form to the State Health Officer.

If the alien does not report by ____ please check here [ ] and forward this form to the State Health Officer. Retain for your records the accompanying report of examination performed abroad.

Military will send direct to the CDC.

Your Initial Evaluation:

A. Direct Smear (in U.S.)
[ ] Positive
[ ] Negative
[ ] Not Done
[ ]Unavailable

B. X-ray (in U.S.)
[ ] Normal
[ ] Abnormal
[ ] Not Done
[ ] Undetermined

C. X-ray (abroad)
[ ] Normal
[ ] Abnormal
[ ] Not Done

D. Presumptive Diagnoses
[ ] Pulmonary TB - Active
[ ] Pulmonary TB - Not Active
[ ] Pulmonary TB - Activity
[ ] Extrapulmonary TB
[ ] Non-TB Abnormality
[ ] No Abnormality

E. Has patient received chemotherapy/prophylaxis in the past?

[ ] Yes **[ ] No** **[ ] Unknown**

F. Are you prescribing chemotherapy/prophylaxis?

[ ] Yes **[ ] No**

Signature of Physician:

Date of Evaluation:

Name of Health Department:

Tuberculin Skin Testing in Schools

Purpose

To establish a policy for tuberculin skin testing (TST) in elementary, and secondary schools.

Policy

Universal tuberculin skin testing (TST) of all students in school settings **is not recommended.** Only children at increased risk of TB exposure should be considered for TST. In Utah, high-risk children include contacts of persons with active TB disease (ATBD), newly arrived foreign-born children from high prevalence areas, children of migrant farm workers, children with socio-economic risk factors such as homelessness, living in a shelter, or caretaker with risks such as IV drug users.

Procedure

a. Decisions regarding implementation of a school-based TST program should be made jointly by local public health professionals in collaboration with school nurses and school administrators. The TB Control Program is available for consultation.

b. A decision to conduct a TST program is a decision to treat latent TB infection (LTBI) if identified and resources are available. Targeted testing of children at high risk for LTBI must be accompanied by a plan for providing necessary follow up. This plan must include resources for providing a chest x-ray, medical evaluation and treatment for LTBI, which includes medication and nursing case management time.

c. It is recommended that new students be assessed for risk factors upon entrance to school.

d. If a TST program is implemented, students with identified risk factors should then be screened with the tuberculin skin test at age 4-6 and 14-16.

e. Evaluation of the data on the number of tests administered, results of the test, number identified with LTBI or ATBD, and number who complete treatment should be reviewed with local health departments (LHDs). If a low prevalence of ATBD or LTBI is identified, decisions to continue the screening program should be re-evaluated.

References

Tuberculosis School Nurse Handbook, New Jersey Medical School, National Tuberculosis Center, 1998.

Utah Department of Health, Bureau of Communicable Disease Control, TB Rule, R388-804-4 Screening priorities and Procedures.

Minnesota Department of Health Guidelines for Decisions Regarding Tuberculosis Screening of Elementary and Secondary School Students.

American Academy of Pediatrics Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents Pediatrics 2004;114; 1175-1201

Follow-up Responsibility

TB Nurse Consultant

Tuberculin Skin Testing in Post Secondary Schools

Purpose

To establish a policy for tuberculin skin testing (TST) in post secondary schools.

Policy

Universal tuberculin skin testing (TST) of all students in school settings is **not recommended**. Targeted tuberculin skin testing is recommended for all international students originating from high prevalence countries. Students whose studies involve **extensive** international travel to high prevalence countries are also candidates for testing prior to travel and 8-10 weeks following their return to the United States.

Procedure

a. Decisions regarding implementation of a school-based TST screening program should be made jointly by local public health professionals in collaboration with school nurses and school administrators. The TB Control Program is available for consultation.

b. A decision to conduct a TST program is a decision to treat latent TB infection (LTBI) if identified and resources are available. Targeted testing of students at high risk for LTBI or active TB disease (ATBD) must be accompanied by a plan for providing necessary follow up. This plan must include resources for providing a chest x-ray, medical evaluation, and treatment for LTBI, which includes medication and nursing case management.

c. Evaluation of the data on the number of tests administered, results of the test, number identified with LTBI or ATBD, and number who complete treatment should be reviewed with local health departments (LHDs). If a low prevalence of ATBD or LTBI is identified, decision to continue the screening program should be re-evaluated.

References

Tuberculosis School Nurse Handbook, New Jersey Medical School, National Tuberculosis Center, 1998.

Utah Department of Health, Bureau of Communicable Disease Control, TB Rule, R388-804-4 Screening priorities and Procedures.

Minnesota Department of Health Guidelines for Decisions Regarding Tuberculosis Screening of Elementary and Secondary School students.

American Academy of Pediatrics Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents Pediatrics 2004;114; 1175-1201

Follow-up Responsibility

TB Nurse consultant

Tuberculin Skin Testing in Dialysis Centers

Purpose:

To establish a process for tuberculin skin testing (TST) clients in Dialysis Centers for latent tuberculosis infection or active tuberculosis disease.

a. Latent tuberculosis infection (LTBI) is defined as a condition in which tuberculosis bacteria are alive but inactive in the body. People with TB infection have no symptoms, don't feel sick, cannot spread TB to others and usually have a positive skin test reaction. They may develop active tuberculosis disease later in life if they do not receive latent tuberculosis infection therapy.

b. Active TB disease (ATBD) is defined as an illness in which tuberculosis bacteria are multiplying and attacking different parts of the body. The symptoms of TB disease include weakness, weight loss, fever, no appetite, chills, and sweating at night. Other symptoms of TB disease depend on where in the body the bacteria are growing. If TB disease is in the lungs (pulmonary TB), the symptoms may include a bad cough, pain in the chest, and coughing up blood.

Policy:

Routine tuberculin skin testing (TST) of hemodialysis clients is recommended.

Rationale: The incidence of tuberculosis in end stage renal disease (ESRD) clients is estimated to be 10-15 times higher than in the general population. This is because ESRD clients are more likely to be elderly or belong to certain minority groups in which TB rates are higher. ESRD clients with latent tuberculosis infection (LTBI) may be more likely to progress to active TB disease (ATBD).

ATBD may be difficult to diagnose with symptoms often attributed to underlying chronic renal disease. Clients receiving hemodialysis spend prolonged periods of time together in health care facilities, thereby increasing the potential for tuberculosis transmission if a person has active disease.

Procedure

a. Each new client entering a dialysis program should be assessed for symptoms of tuberculosis and risk factors for tuberculosis.

b. A Mantoux tuberculin skin test should be placed by a trained professional unless there is a documented history of a previous positive skin test.

c. Tuberculin skin testing is not contraindicated for BCG vaccinated persons.

d. If the tuberculin skin test is negative, a second test should be placed in 1-3 weeks.

e. Each new client with an identified risk factor for tuberculosis should also have a chest x-ray regardless of skin test results.

f. Active TB disease should be considered with abnormal x-ray results if the client is:

- From an area of high incidence of tuberculosis
- The skin test result is >5mm
- There is known exposure to person with active TB disease

g. Any client with a positive tuberculin skin test or a documented history of a previous positive tuberculin skin test should be evaluated for treatment and started on isoniazid (INH) if appropriate.

h. Any client placed on INH for LTBI should be considered for directly observed therapy (DOT).

i. Questions regarding dosing and timing of INH with dialysis should be directed to the TB Control Program at (801) 539-6096 or the local health department.

References

CDC Core Curriculum on Tuberculosis, What the clinician should Know, fourth Edition, 2000. (Page 25-33)

Utah Department of Health Tuberculosis Control/Refugee Health, A Guide to the Classification of Mantoux Tuberculin Skin Test (TST) Results and the Management of TST-Positive and Other Clients.

Follow up Responsibility

TB Nurse Consultant

Disease Reporting

Purpose

The purpose of these reporting requirements is to focus efforts on tuberculosis control and disease elimination. The standards outlined constitute the minimum expectations.

Policy

The following is a summary of reportable conditions related to tuberculosis in the state of Utah:

Condition/Test Result	Reportable by Whom
Confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed by laboratory test	Physicians, health care providers, hospitals, other similar private or public institutions, or any other person providing treatment to the confirmed or suspected case **must report within 24 hours to the TB Control Program or Local Health Department.** A report of test results by a laboratory does not relieve the attending physician/ health care worker of his/her reporting obligation.
Sputum smears positive for acid-fast bacilli (AFB) and cultures positive for *Mycobacterium tuberculosis* (MTB)	All laboratories that perform TB testing and in-state laboratories that send specimens for out-of-state testing **must report within 24 hours to the TB Control Program or Local Health Department.** A report by the physician/health care worker does not relieve the laboratory of its reporting obligation.
A tuberculin skin test result of 5mm induration or more, if it occurs in a health care worker, correctional facility worker, or detention facility worker who has had close contact to a known TB case.	Physicians, health care providers and health care facilities **must report within 7 days to the TB Control Program or Local Health Department.**
Any active TB disease client on directly observed therapy that has missed one dose.	Medical providers and health care organizations **must report within 7 days to the TB Control Program or Local Health Department.**

Procedure:

The TB Control Program will need the following information regarding a reported confirmed/suspect TB case.

Name
Date of birth
Address
Sex
Race/ethnic origin
Marital status
Site of disease
Symptoms/onset dates
Hospital admission information
Bacteriology results, date(s), and name of laboratory performing test(s)
X-ray results (if applicable)
HIV testing information
TB skin test results (in mm) and date of test
Drug therapy (medications used, dates given)
Type of isolation/quarantine arrangements
Other pertinent medical & epidemiological information
Provider's names/addresses/telephone numbers

Whom to Notify Regarding Active/Suspect TB:

All cases, suspect cases and positive laboratory results must be reported within 24 hours to the local health department or the TB Control Program.

Telephone report to Utah Department of Health, TB Control Program at (801) 538-6096. Fax reports to (801) 538-9913.

References

Special Measures for the Control of Tuberculosis, Rule R388-804.

Follow-up Responsibility

TB Nurse Consultant
TB Control Program Manager

Tuberculosis Outbreak Response Plan

Purpose

The purpose of this plan is to ensure adequate and timely response to TB outbreaks by outlining the roles of the Utah Department of Health, Bureau of Communicable Disease Control, and the local health departments. These actions will include TB outbreak evaluation and management, especially in low morbidity areas in Utah. The goal of this plan is to prevent the potential of TB transmission in schools, workplaces, or community settings. Indications for executing the outbreak plan include: when the observed rate of TB disease in a geographical area exceeds the normal (endemic) rate, or a single case of unusual (e.g. multi-drug resistant) TB occurs.

Policy

When endemic levels have been exceeded, the manager of the TB Control Program will declare an outbreak after consultation with the State Epidemiologist, and local health officer. At that time, the Outbreak Response Team will implement the Utah State Outbreak Response Plan.

Procedure

The procedure for responding to an outbreak is outlined in detail as part of the Utah State TB Outbreak Response Plan. This document has been included as a reference.

References

Utah State TB Outbreak Response Plan, Utah Department of Health, 2001.

Follow-up Responsibility

TB Control Program Manager

Program Resources

Purpose

A purpose of the TB Control Program is to provide enhanced TB treatment and public health follow-up for those diagnosed with latent TB infection (LTBI) or active TB disease (ATBD). All newly diagnosed cases of ATBD will receive the appropriate evaluation, treatment, follow-up and incentives/enablers necessary to complete treatment within 12 months of diagnosis (unless a multi-drug resistant case). Screening activities (to include evaluation of symptoms, tuberculin skin test, and chest x-ray) will be provided for contacts of cases and migrant school children and their families.

Policy

The TB Control Program provides funding for TB medications, pharmacy dispensing fees and administrative costs, at no charge to clients with no insurance coverage, for the treatment of TB disease and infection through local health departments.

The TB Control Program will provide incentives to encourage clients to complete a prescribed course of TB treatment. Appropriate incentives include food coupons, limited housing expenses, time limited utility expenses, clothing, household items, or others which are deemed appropriate by the nurse consultant and case manager and receive prior approval by the program manager.

Medical and pharmaceutical consultants who specialize in the diagnosis and treatment of tuberculosis infection and disease are available to provide technical advice.

Procedure

For those services covered under local health department contracts, request for payment should be submitted on a Monthly Expenditure Report.

Direct reimbursement for pre-authorized services can be completed by submitting a detailed summary of expenses and original statements to the TB Control Program (i.e., rent expenses, utility expenses, limited hospital expenses). Request for food coupons and/or other incentives can be requested by telephoning staff of the TB Control Program (Documentation of clients receiving food coupons is required).

Medical consultants may either be contacted by local health department staff or through the state health department nurse consultant. Billing for consulting services is done directly between the consultant and the state health department. Pharmaceutical questions should be referred through the state health department nurse consultant.

References

Local Health Department Contracts
CDC Enablers and Incentives, August 1989.

Follow-up Responsibility

TB Nurse Consultant
TB Control Program Manager

Ordering Anti-tuberculosis Medication

Purpose

To establish a policy for ordering and obtaining medication for tuberculosis.

Policy

The Tuberculosis Control Program provides anti-tuberculosis medications for suspected and active TB disease cases and for the treatment of latent tuberculosis infection at no expense to the client who lacks medical coverage to pay for these medications.

Procedure

a. Local health departments shall establish a relationship with a local pharmacy to provide dispensing services.

b. Medications will only be provided to approved pharmacies. Minimum inventories will be maintained at each pharmacy to allow sufficient access for clients.

c. The purchase of anti-tuberculosis medication is based upon funding availability. Should funding become impacted these services may be reduced or eliminated. The TB Control Program reserves the right to make decisions on client eligibility based on current medical practice, fund availability and recommendations from the most current treatment guidelines endorsed by the American Thoracic Society and the Centers for Disease Control and Prevention.

Follow up Responsibility

TB Program Health Program Representative

Required Reports and Forms

Purpose

To establish a policy for required reports and forms for the TB Control Program.

Policy

The TB Control Program requires the following reports from local health departments: 1) Monthly TB Skin Test Report, 2) Monthly TB Activity Report, 3) Aggregate Reports for Tuberculosis Program Evaluation (ARPE), 4) Report of Verified Case of Tuberculosis (RVCT). While forms generated at the local health department level may be of assistance in documentation of TB evaluation, treatment for latent TB infection (LTBI) or active TB disease (ATBD), they are not required to be sent to the TB Control Program.

Procedure

a. The Monthly TB Skin Test Report is required for agencies receiving PPD from the TB Control Program and the Monthly TB Activity Report and Pharmacy Inventory is required for agencies receiving medication from the program. The completed reports are due by the 10th of each month for the previous month and can be faxed, mailed or e-mailed.

b. The TB Nurse Consultant will send a CI Record form to case managers of suspect and ATBD cases. These reports document follow up testing and treatment of contacts. The case manager should return the completed form to the TB Program Nurse Consultant at 30 days, 120 days and when all contacts have completed treatment for LTBI.

c. The Report of Verified Case of Tuberculosis (RVCT) is completed on new cases of ATBD. The TB Nurse Consultant completes this with the case manager by telephone when the case is confirmed.

d. Sample forms recommended to assist the case manager in accurate record keeping are listed under the forms section on the TB Program Web page.

References

Guide for Completing Monthly TB Activity Report
Contact Investigation Record

Follow up Responsibility

TB Control Program Epidemiologist

Site Visits

Purpose

To establish a policy for site visits to local health department by the TB Control Program.

Policy

Tuberculosis services are provided in a variety of settings. The official agency, the Utah Department of Health, is charged by law with the responsibility of overseeing the control of TB. Public health's oversight role has been expanded even further beyond mandatory reporting of cases and ensuring completion of treatment. Health department TB control programs are reviewing the quality of the diagnostic, treatment, and prevention services given to clients. The quality of care and effectiveness of the TB program is reviewed and evaluated in the following ways: telephone consultation, reports, site visits, and cohort review.

Procedure

a. The TB Control Program will contact the local health department (LHD) nursing director and TB nurse to schedule a site visit.

b. The TB Clinic Structure and Management Form will be used to evaluate the LHD TB Program and services provided. See Site Visit Tool under forms.

c. A report of findings of the site visit will be sent to the health officer, nursing director and TB nurse.

d. The site visit will be utilized for the TB Control Program staff to meet with TB nurses in their environment, to provide consultation and education as indicated, and to strengthen the partnership of the agencies.

References

Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Standards of Care. The National Tuberculosis Controllers Association, First edition 1997.

Follow up Responsibility

TB Nurse Consultant

EDUCATION

Purpose

To promote the Centers for Disease Control and Prevention and the American Thoracic Societies guidelines for Tuberculosis control/elimination in the United States.

Policy

a. The TB Control Program provides training, education, and expert consultation to local health departments and others involved with TB control/prevention in Utah. This would include:

- Mantoux Tuberculin Skin Testing Certification
- Educational presentations on Tuberculosis
- Educational material design and development
- In-services, technical assistance, and expert consultation on state-of-the-art TB information, standards, and policies

Procedure

To access these services please contact:

TB Control/Refugee Health Program
Utah Department of Health
Box 142105
Salt Lake City, Utah 84114-2105
(801) 538-6096
www.health.utah.gov/cdcl

References

The Centers for Disease Control and Prevention
Division of Tuberculosis Elimination
Office of Communications, NCHSTP
1600 Clifton Road NE
Mailstop E-07
Atlanta, Georgia 30333
(404) 639 - 8063
www.cdc.gov/nchstp/tb/

Follow-up responsibility

TB Health Educator

Internet Resources for TB

The Internet is one of the quickest and easiest ways to locate accurate information on TB. The following is a list of Web Sites that may be useful.

American Thoracic Society
www.thoracic.org/

Brown University TB-HIV Research Laboratory
tbhiv.biomed.brown.edu/website/

Centers for Disease Control and Prevention, Division of Tuberculosis Elimination
www.cdc.gov/nchstp/tb/

EthnoMed
www.ethnomed.org/

Francis J. Curry National Tuberculosis Center
www.nationaltbcenter.edu/

International Union Against Tuberculosis and Lung Disease
www.iuatld.org/

National Institute for Occupational Safety and Health
www.cdc.gov/niosh/topics/respirators/

National Jewish Medical and Research Center
www.nationaljewish.org/

National Library of Medicine
www.ncbi.nlm.nih.gov/PubMed/

New Jersey Medical School, National Tuberculosis Center
www.umdnj.edu/ntbc/ntbcfrhm.html

Occupational Safety and Health Administration
www.osha.gov/SLTC/tuberculosis/index.html

Stanford Center for Tuberculosis Research
www.stanford.edu/group/molepi/

Surveillance of Tuberculosis in Europe
www.eurotb.org/

Utah Department of Health, TB Control/Refugee Health Program
health.utah.gov/els/hivaids/tb/tbrefugee.html

WHO Global TB Programme
www.who.int/tb/en/

The Stop TB Partnership
www.stoptb.org

TB Education & Training Resources
www.findtbresources.org

MEDICAL INTERPRETERS/TRANSLATORS

Purpose

To promote the Office for Civil Rights policy guidance on the Title VI prohibition against national origin discrimination as it affects persons with limited English proficiency.

Policy

Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin by any entity that receives federal financial assistance. Under Title VI of the law, hospitals, Health Care Maintenance Organizations, social services and other entities that receive Federal financial assistance from the Department of Health and Human Services (HHS) are required to take the steps necessary to ensure that individuals with limited English proficiency (LEP) can meaningfully access the programs and services. The requirements apply to state-administered, as well as private and non-profit facilities and programs, that benefit from HHS assistance. The Office for Civil Rights is responsible for compliance with the law as it applies to HHS assisted programs.

Procedure

Interpreting/translating services can be found in the yellow pages under “Translators & Interpreters.” There are also Medicaid funded interpreters available.

References

Utah Department of Health Medicaid
Box 143101
Salt Lake City, Utah 84114-3101
1-800-662-9651
www.medical interpreters

The Department of Health and Human Services
Office for Civil Rights
Carole Brown or Ronald Copeland
Room 506F
200 Independence Avenue, S.W.
Washington D.C. 20201
(202) 619-0805
TDD 1-800-537-7697
www.hhs.gov/ocr/
LEP Guidance and Policy

Follow up Responsibility

Refugee Health Program Specialist

Staff Responsibility

TB Controller (Cristie Chesler, BA): This individual is responsible for policy direction regarding the TB Control Program within the State of Utah.

Program Manager (Cristie Chesler, BA): This individual is responsible for program administration of Tuberculosis Control Program activities, contract oversight, and supervising Program employees.

RN III (June Oliverson, RN): This individual is responsible for TB case management, coordination with local health departments, and targeted testing outreach.

Epidemiologist II (Jerry Carlile, MSPH): This individual is responsible for the TB surveillance system, provides technical assistance to local health departments in establishing surveillance networks, and is responsible for TB statistical report generation and dissemination.

Health Program Specialist (Genevieve Greeley, BS CHES): This individual assists with tuberculin skin test certification, publishes newsletters, and coordinates annual conferences. This person also provides TB education to providers throughout the state.

Health Program Representative (Bonnie Jones): This individual is responsible for the data management and the medication program for the TB Control Program.

Information Analyst (Leslie Clark): This individual is responsible for maintaining the Tuberculosis Information Management System (TIMS) database and submitting monthly electronic reports to the Centers for Disease Control and Prevention.

State Consultants

The following state consultants may be contacted by public health and healthcare practitioners only:

Richard E. Kanner, MD	Infectious Disease 801-581-7806
Wayne Samuelson, MD	Infectious Disease 801-581-7806
Gary Alexander, MD	Infectious Disease 801-773-4840
Krow Ampofo, MD	Pediatric Infectious Disease 801-581-6791
Paul Swoboda, MD	Salt Lake Family Health 801-350-4479
Mara Rabin, MD	Salt Lake Family Health 801-350-4479

Glossary of Terms

Acid-fast bacilli (AFB) - Organism that retain certain stains, even after being washed with acid alcohol. Most acid-fast organisms are mycobacterium. When AFB is seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be considered a possibility.

Active TB Disease (ATBD) - clinical and/or radiographic evidence of current TB. Established most definitively by isolation of *M. tuberculosis* on culture.

Adherence - Following the recommended course of treatment by taking all the prescribed medications for the entire length of time necessary to adequately treat the disease or infection.

Anergy - Inability to mount a delayed-type hypersensitivity response to one or several skin-test antigens as a result of immunosuppression from disease (e.g., HIV infection) or immunosuppressive drugs (chemotherapy, organ transplant medication).

Antigen - Any substance that is capable under the appropriate conditions of inducing a specific immune response and of reacting with the products of that response; that is, with specific antibodies or specifically sensitized T-lymphocytes or both. Purified protein derivative (PPD) is one such antigen that induces an immune response when antibodies react to the protein of the tubercle bacillus in the body. Thus, a positive tuberculin skin test is produced, as evidenced by an induration at the antigen injection site.

ATS - American Thoracic Society.

Atypical - Also know as “atypicals”, mycobacterium other than TB (MOTT), and non-tuberculous mycobacterium (NTM). Members of the mycobacteria family, but not TB.

BACTEC (radiometric method) - A rapid culture method using radioactive carbon dioxide. Identification of the mycobacterial organism can take place in as little as 10 days.

Bacteriological examination - Test done in a mycobacteriology laboratory to diagnose TB disease; includes examining a specimen under a microscope, culturing the specimen, and doing drug susceptibility testing.

BCG - (Bacillus of Calmette and Guérin) - An organism of the strain *Mycobacterium bovis* rendered avirulent in a vaccine given to humans to prevent TB disease. Used primarily in countries other than the United States. Not routinely used in the United States because it has not been determined to be effective in adults. Considered for use only with select persons who meet specific criteria. May be effective in preventing TB meningitis in children.

Booster phenomenon - One to three weeks after an initial negative tuberculin skin test, a second test is administered, resulting in a positive tuberculin skin test reaction. This phenomenon is the result of the immune system being "boosted" to remember the tubercle protein in situations where there is slight immune suppression due to age or illness.

Case reporting - Informing the state or local health department when a new case (an occurrence) of TB disease has been diagnosed or is suspected.

Cavity - A hollow space in the lung and destruction of lung tissue caused by *Mycobacterium tuberculosis*; contains millions of tubercle bacilli.

CDC - Centers for Disease Control and Prevention.

Cell-mediated immunity - Immunity in which the participation of lymphocytes and macrophages is predominant. A localized reaction.

Colonization - The development of colonies (collections or groups of bacteria) in a culture derived from the reproduction of an isolated single organism or group of organisms; or the development of cells in a part of the body to which they have been carried.

Compliance - Ongoing cooperation by clients in all aspects of the treatment regimen as prescribed by the medical provider.

Contact - Person who has shared the same air space with a person with infectious TB for a sufficient period of time to make transmission of infection likely.

Contact (casual) - Person who has shared the same air space with a person with infectious TB, but is at low risk of developing infection with *M. tuberculosis* because of the length of time and/or the intensity of exposure.

Contact (close) - Person who has shared the same air space with a person with infectious TB, but is at high risk of developing infection with *M. tuberculosis* because of the length of time and/or the intensity of exposure.

Contact (high-risk) - Same as close contact.

Contact (household) - Person who has shared air with the index case in a living situation.

Contact Investigation - A methodical, epidemiological study conducted with or for each newly reported index case of active TB disease.

Contact (low-risk) - Same as casual contact.

Containment - Stopping the spread of tuberculosis. Aggressively treating persons with ATBD, treating persons with LTBI, and applying effective infection control measures.

Conversion (tuberculin skin test) - A term suggested to designate the change from a tuberculin negative to tuberculin positive state. An increase of $10mm in skin test reaction size within a 2 year interval.

Conversion (sputum) - In response to effective treatment, serial sputum tests convert from positive to negative. Conversion is considered to have occurred when there have been three consecutive negatives, after positive specimens have been identified. True conversion means that there is no reversion to positive.

Culture - Organisms grown on media (substances containing nutrients) so that they can be identified; a positive culture for *M. tuberculosis* contains tubercle bacilli, whereas a negative culture contains no detectable tubercle bacilli.

Delayed-Type Hypersensitivity (DTH) - a slowly developing cell-mediated immune response to a specific antigen.

Directly Observed Therapy (DOT) - A compliance-enhancing strategy in which a professional, lay worker, or other responsible person observes the client take each dose of medication.

Directly Observed Therapy for LTBI - DOT for clients with Latent TB Infection.

Disseminated TB - Occurring at more than one site in the body as a result of hematogenous spread. Indicates some failure of the immune system to control the spread to one site.

Droplet nuclei - Microscopic particles (1-5 microns), produced by respiratory actions, such as coughing and sneezing that carry the tubercle bacilli and remain airborne by normal air currents in a room.

Drug resistance - Inability of anti-TB medications to kill *M. tuberculosis* organisms.

Drug susceptibility - Ability of anti-TB medications to kill *M. tuberculosis* organisms.

Enablers - Anything that assists the client to more readily complete therapy.

Engineering controls - Engineering systems used to prevent the transmission of TB in health care facilities, including ventilation, high-efficiency particulate air (HEPA) filtration, and ultraviolet germicidal irradiation.

Erythema - Acute inflammatory reaction, caused by vasodilation and congestion of the capillaries (redness) at tuberculin skin test site. Not indicative of a positive tuberculin reaction.

Exposure - The amount and intensity of time spent with someone who has infectious TB disease.

Extrapulmonary - Refers to sites of clinically active TB located outside the lung parenchyma. Two exceptions are pleural TB and TB located in the hilar lymph nodes of the lungs. While these are also part of the lungs, they are considered extrapulmonary when counted as cases.

False-negative reaction - A negative reaction to the tuberculin skin test in a person who has TB infection. May be caused by anergy, recent infection (within the past 10 weeks), very young age (<6 months old), or recent administration of a live virus vaccination.

False-positive reaction - A positive reaction to the tuberculin skin test in a person who does not have TB infection. May be cause by infection with nontuberculous mycobacteria or by vaccination with BCG.

Genetic probe - Rapid method of identifying species of mycobacteria, utilizing genetic probes that are bound to specific pieces of mycobacterial DNA/RNA. Used in place of standard biochemical tests to identify mycobacteria grown in culture.

HEPA (High efficiency particulate air) filter - Specialized filter that is capable of removing 99.97% of particles $3 micron in diameter. Filters may be used in ventilation systems or in personal respirators to filter air. HEPA ventilation systems require expertise in installation and maintenance.

High Risk Congregate Settings – High risk environments are settings where: a) persons who have infectious TB are more likely to live, b) environmental characteristics are conducive to transmission and c) many susceptible persons are at risk for prolonged exposure to potentially infectious clients . This includes prisons and jails, nursing homes and other long-term health care facilities, homeless shelters and residential settings.

Incentives - Rewards in return for adherence with medical regimen.

Incidence - The number of cases of disease having their onset during a prescribed period of time. It is often expressed as a rate (for example, the incidence of measles per 1000 children 5-15 years of age during a specified year). Incidence is a measure of morbidity or other events that occur within a specified period of time.

Index case - The initial individual whose condition leads to the investigation of TB.

Induration - Immune response to a particular antigen involving lymphocyte sensitization and cellular infiltration. It is a firm, raised, usually round bump at the site of injection.

Infectious - Capable of being communicated; capable of spreading infection.

Infiltrate - The formation of a group of tuberculosis cells and bacilli in a tissue; commonly observed on x-ray.

Intermittent therapy - Refers to once-weekly, twice-weekly or thrice-weekly directly observed treatment such as DOT. Not recommended as an unobserved method of treatment, because the client will miss large doses of medicine should he/she become non-compliant.

Intradermal - Referring to placement of the tuberculin skin test with the Mantoux method, just beneath the top surface of the skin.

Isolation - The physical separation of the infected person from others to prevent transmission of TB.

Latent TB Infection (LTBI)- Condition in which living tubercle bacilli are present in an individual, without producing clinically active disease. Infected individual usually has a positive tuberculin skin test, a normal chest x-ray, does not have symptoms related to the infection, and is not infectious.

Liver Function Tests (LFT) - Serological testing used to detect damage to the liver.

Mantoux tuberculin skin test (TST) - Diagnostic tuberculin skin test using an intradermal injection of 5 tuberculin units (T.U.) purified protein derivative (PPD). Method of choice for screening purposes.

Miliary TB - TB disease that occurs when tubercle bacilli enter the bloodstream and are carried to all parts of the body, where they grow and cause disease in multiple sites.

Multidrug-resistant TB (MDR TB)- TB that is resistant to isoniazid and rifampin: more difficult to treat than drug-susceptible TB.

Multiple puncture skin test - Skin test using a device that contains small prongs that are dipped in either O.T. (old tuberculin) or 5 TU PPD. These are pressed onto the skin with the prongs breaking the surface and depositing a nonspecific amount of the skin testing material into the skin. Not acceptable for screening purposes.

Mycobacterium tuberculosis complex - The complex of mycobacterial species that cause TB. Includes *M. tuberculosis*, *M. bovis*, and *M. africanum*.

Non-compliant - Not adhering to the treatment regimen.

Nontuberculous mycobacteria (NTM) - Also known as atypical mycobacteria or MOTT (mycobacterium other than tuberculosis). Members of the mycobacteria family other than *M. tuberculosis*. Some of the more prominent members are *M. avium*, *M. intracellulare*, *M. kansasii*, *M. fortuitum*, etc.

Purified Protein Derivative (PPD) - Material used in tuberculin skin testing using the Mantoux method. Consists of tubercle protein that has been killed by heat and placed in a special diluent for skin testing. Produces an immune response (delayed-type hypersensitivity) if TB infection is present in the body.

Prevalence - The total number of cases of a disease that are present at a certain point in time.

Quarantine - Using public health laws to confine an uncooperative contagious client in his home or in a facility.

Relapse - The return of disease after a partial recovery from the disease.

Smear - A specimen that has been smeared onto a glass slide, stained, washed in an acid solution, and then placed under the microscope for examination. Used to detect acid-fast bacilli in a specimen.

Sputum smear-positive - Having acid fast bacilli (AFB) that is visible after staining when viewed under a microscope. Individuals who are sputum smear-positive for AFB are considered more infectious than those with sputum smear-negative.

Source case - The infectious person who is believed to have transmitted infection to the index case.

Surveillance - Activities related to finding cases of disease or injury, guiding them into the health care system, and maintaining records on their cases for such purposes as identifying high-risk groups and trends in morbidity and related mortality. Includes activities related to identifying and maintaining records on persons with tuberculosis infection as well, in order to identify candidates for medication and, in institutional settings, to identify the quality of infection control practices.

Susceptibility testing - Refers to the laboratory testing done on mycobacterial cultures to determine susceptibility of the organisms to specific anti-TB drugs. Should be done on initial positive culture, and on certain subsequent cultures should the emergence of drug resistance be suspected.

Transmission - The spread of an organism, such as *M. tuberculosis*, from one person to another. Factors to consider include contagiousness of the patient, the type of environment, and the length of exposure.

Tubercle bacilli - Term often used to refer to organism of the *Mycobacterium tuberculosis* complex.

Tuberculin skin test - A method for demonstrating infection with *M. tuberculosis* in which an antigenic protein (PPD) from cultures of *M. tuberculosis* is introduced into the skin intradermally.

Tuberculosis - An infectious disease of man and animals caused by the species *Mycobacterium tuberculosis* and characterized by the formation of tubercles and caseous necrosis in the tissues.

Two step skin testing - Refers to the “booster test” in which a second skin test is given 1-3 weeks after an initial negative test. The purpose is to “boost” the immune system to recognize tubercle protein, if infection is actually present in the body but suppressed due to age or illness. Recommended when repeat testing is required such as with health care workers.

Wheal - A discrete, pale elevation of the skin as a result of the intradermal injection of 5 TU PPD for the purpose of tuberculin skin testing

Classification System for TB

Class	Type	Description
0	No TB exposure Not infected	No history of exposure Negative reaction to tuberculin skin test or QuantiFERON-TB test
1	TB exposure No evidence of infection	History of exposure Negative reaction to tuberculin skin test or QuantiFERON-TB test
2	TB infection No disease	Positive reaction to tuberculin skin test or QuantiFERON-TB test Negative bacteriological studies (if done) No clinical, bacteriological, or radiographic evidence of active TB
3	TB, clinically active	*M. tuberculosis* cultured (if done) Clinical, bacteriological, or radiographic evidence of current disease
4	TB Not clinically active	History of episode(s) of TB **or** Abnormal but stable radiographic findings Positive reaction to the tuberculin skin test or QuantiFERON-TB test Negative bacteriologic studies (if done) **and** No clinical or radiographic evidence of current disease
5	TB suspected	Diagnosis pending